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Supreme Court, U.S.
FILED

No. 07-_____ 071327 APR 18 2008

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In The
Supreme Court of the United States

ALBERTSON'S, INC., *et al.*,

Petitioners,

v.

JENNIFER KANTER, *et al.*,

Respondents.

On Petition For A Writ Of Certiorari To The California Supreme Court

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Seventy years ago, Congress decided that "all . . . proceedings for the enforcement, or to restrain violations, of [the Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act")] shall be by and in the name of the United States." 21 U.S.C. § 337(a). In 1990 amendments to the FDCA, Congress created a narrow, secondary enforcement role for state governments. It allowed states to enact laws identical to specified portions of the FDCA, *id.*, § 343-1, and also permitted state governments to enforce certain FDCA provisions in federal court under certain conditions, *id.*, § 337(b). Congress, however, has never permitted the private enforcement of FDCA requirements. The California Supreme Court nonetheless held that Respondents, private plaintiffs, could bring a class action to enforce the FDCA under the aegis of state law.

The question presented is: Are private parties' state law claims to enforce FDCA requirements preempted by Congress' mandate that the Act be enforced only by the federal or state governments?

PARTIES TO THE PROCEEDING

Petitioners are Albertson's, Inc., Safeway Inc., The Kroger Co., T.A.C.T. Holding, Inc., Trader Joe's Company, Bristol Farms, Inc., Ocean Beauty Seafoods, Inc., Whole Foods Market California, Inc., and Mrs. Gooch's Natural Foods Market, Inc.

Respondents are Jennifer Kanter, Ben Betts, Ellyn Gerson, David Matsumoto, Lyta Jocum, Julian Carroll, Arleen Rovere, Monique Gauthier, Ivania Lourdes Flores, Sheila Malone, Pastor Romney Bernadette Darkin, and Cesar Tercero Alonzo.

RULE 29.6 STATEMENT

SUPERVALU INC., a publicly traded company, is the parent and owns the stock of New Albertson's, Inc. which consists of the core supermarket businesses owned by Albertson's, Inc. at the time this lawsuit was filed. New Albertsons, Inc. is an active corporation and a wholly owned subsidiary of SUPERVALU INC. No publicly held company owns 10% or more of the stock of SUPERVALU INC.

SUPERVALU INC. is also the parent and owns the stock of New Bristol Farms, Inc., which consists of the core supermarket businesses owned by Bristol Farms, Inc. at the time this lawsuit was filed. When New Bristol Farms, Inc. was an active corporation, it was a wholly owned subsidiary of SUPERVALU INC. SUPERVALU INC. is currently the parent and owns the stock of Bristol Farms, Inc.

RULE 29.6 STATEMENT – Continued

Safeway Inc. ("Safeway") is a publicly traded company. AXA Assurances I.A.R.D. Mutuelle (a French mutual insurance company), AXA Assurances Vie Mutuelle (a French mutual insurance company), AXA Courtage Assurance Mutuelle (a French mutual insurance company, and along with the first two acting as a parent holding company), AXA (a French company and parent holding company), and AXA Financial, Inc. (a Delaware corporation and parent holding company) beneficially owned 77,820,579 shares of Safeway common stock as of August 31, 2007, representing 17.7% of Safeway's outstanding shares. AllianceBernstein L.P. (a subsidiary of AXA Financial, Inc. organized under the laws of the State of Delaware) is deemed to have sole dispositive power over 77,258,207 of those shares.

The Kroger Co. is a publicly traded company. No publicly held company owns 10% or more of its stock.

Trader Joe's Company is owned entirely by T.A.C.T. Holding, Inc., a privately held company. There are no parent corporations of T.A.C.T. Holding, Inc. and no publicly held company owns more than 10% of T.A.C.T. Holding, Inc.

Mrs. Gooch's Natural Foods Market, Inc. and Whole Foods Market California, Inc. are 100% wholly owned subsidiaries of Whole Foods Market, Inc., which is a publicly traded company. No publicly held company owns 10% or more of its stock.

RULE 29.6 STATEMENT – Continued

Ocean Beauty Seafoods LLC is an Alaska limited liability company owned 50% by Ocean Beauty Holdings, Inc., a Washington corporation formerly known as Ocean Beauty Seafoods, Inc., and 50% by Bristol Bay Economic Development Corporation, an Alaska nonprofit corporation.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
PARTIES TO THE PROCEEDING	ii
RULE 29.6 STATEMENT	iii
OPINIONS BELOW	1
JURISDICTION	1
STATUTORY PROVISIONS INVOLVED	1
STATEMENT OF THE CASE	3
A. THE FEDERAL STATUTORY SCHEME	4
1. Congress' Original Plan Mandated Exclusive Federal Enforcement and Unequivocally Prohibited Private Enforcement	4
2. Congress' 1990 Amendments Created A Limited Role For State Governments, But None For Private Parties	5
B. PROCEDURAL HISTORY	8
1. The Trial Court's Decision Dismissing Respondents' Case On Federal Preemption Grounds	9
2. The California Court Of Appeal's Decision Unanimously Affirming The Trial Court's Dismissal On Federal Preemption Grounds	10
3. The California Supreme Court's Decision Allowing Respondents' Private FDCA Claims To Proceed	11

TABLE OF CONTENTS – Continued

Page

REASONS FOR GRANTING THE PETITION..... 12

I. THE CALIFORNIA SUPREME COURT'S DECISION CONFLICTS WITH CONGRESS' PROHIBITION AGAINST PRIVATE FDCA ENFORCEMENT ACTIONS AND THIS COURT'S DECISION IN *BUCKMAN* UPHOLDING THAT PROHIBITION..... 13

A. FDCA Section 337 Reflects Congress' Unmistakable Intent To Preclude *All* Private Enforcement Actions, As This Court And Many Lower Courts Have Recognized..... 13

B. Congress' Longstanding Ban On Private Enforcement Actions Was Unaffected By FDCA Section 343-1..... 19

II. THE CALIFORNIA SUPREME COURT'S DECISION WILL HAVE PROFOUNDLY NEGATIVE CONSEQUENCES THROUGHOUT THE COUNTRY..... 21

CONCLUSION..... 27

TABLE OF CONTENTS – Continued

Page

APPENDIX

Farm Raised Salmon Cases, 42 Cal. 4th 1077, 175 P.3d 1170 (2008) ..... App. 1

Farm Raised Salmon Cases, 142 Cal. App. 4th 805 (2006) ..... App. 36

Farm Raised Salmon Cases, Order Sustaining Joint Demurrer With Leave To Amend, Superior Court of the State of California for the County of Los Angeles, Case No. JCCP 4329 (Jan. 13, 2005) ..... App. 51

Excerpts of House Debate on H.R. No. 3562, 101st Cong., 2d Sess., 136 Cong. Rec. 1539 (daily ed. July 30, 1990) ..... App. 66

Excerpts of H.R. Rep. No. 101-538, 2d Sess. (1990) ..... App. 72

TABLE OF AUTHORITIES

Page

FEDERAL CASES

Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp., 626 F. Supp. 278 (D. Mass. 1986) 5

Anthony v. Country Life Mfg., L.L.C., No. 02C1601, 2002 WL 31269621 (N.D. Ill. Oct. 9, 2002) 16

Autin v. Solvay Pharmaceuticals, Inc., No. 05-2213, 2006 WL 889423 (W.D. Tenn. Mar. 31, 2006) 15

Bailey v. Johnson, 48 F.3d 965 (6th Cir. 1995) 14, 15, 22

Bates v. Dow Agrosciences LLC, 544 U.S. 431 (2005) 20, 21

Braintree Labs., Inc. v. Nephro-Tech, Inc., No. 96-2459, 1997 WL 94237 (D. Kan. Feb. 26, 1997) 16

Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001) ..... *passim*

California v. ARC America Corp., 490 U.S. 93 (1989) 19

Chroniak v. Golden Investment Corp., 983 F.2d 1140 (1st Cir. 1993) 24

Ethex Corp. v. First Horizon Pharmaceutical Corp., 228 F. Supp. 2d 1048 (E.D. Mo. 2002) 16

Fraker v. KFC Corp., No. 06-CV-01284, 2007 WL 1296571 (S.D. Cal. Apr. 30, 2007) 12, 15

TABLE OF AUTHORITIES – Continued

Page

Healthpoint, Ltd. v. Ethex Corp., 273 F. Supp. 2d 817 (W.D. Tex. 2001) 15, 17

In re Orthopedic Bone Screw Products Liability Litig., 193 F.3d 781 (3d Cir. 1999) 14

In re Scrimpsher, 17 B.R. 999 (Bankr. N.D.N.Y. 1982) 24

Keene Corp. v. United States, 508 U.S. 200 (1993) 14

Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) 20, 21

Monessen Southwestern Ry. Co. v. Morgan, 486 U.S. 330 (1988) 18

National Women's Health Network, Inc. v. A. H. Robins Co., 545 F. Supp. 1177 (D. Mass. 1982) ..... *passim*

Pacific Trading Co. v. Wilson & Co., Inc., 547 F.2d 367 (7th Cir. 1976) 5, 14

PDK Labs, Inc. v. Friedlander, 103 F.3d 1105 (2d Cir. 1997) 15

Reliance Electric Co. v. Emerson Electric Co., 404 U.S. 418 (1972) 21

Reyes v. McDonald's Corp., Nos. 06 C 1604, 06 C 2813, 2006 WL 3253579 (N.D. Ill. Nov. 8, 2006) 17, 25

Summit Tech., Inc. v. High-Line Medical Instruments Co., 922 F. Supp. 299 (C.D. Cal. 1996) 15

TABLE OF AUTHORITIES – Continued

Page

Tuckish v. Pompano Motor Co., 337 F. Supp. 2d 1313 (S.D. Fla. 2004) 23

United States v. Donovan, 429 U.S. 413 (1977).....21

United States v. Hunter Pharmacy, Inc., 213 F. Supp. 323 (S.D.N.Y. 1963) 22

United States v. Sullivan, 332 U.S. 689 (1948) 22

Vermont Pure Holdings, Ltd. v. Nestle Waters North America, No. Civ.A. 03-11465, 2006 WL 839486 (D. Mass. Mar. 28, 2006) 17, 25

STATE CASES

Ai v. Frank Huff Agency, Ltd., 607 P.2d 1304 (Haw. 1980).....23

Barquis v. Merchants Collection Assn., 7 Cal. 3d 94 (1972).....8

Cheshire Mortgage Service, Inc. v. Montes, 612 A.2d 1130 (Conn. 1992).....23

Ganson v. Vaughn, 735 N.E.2d 483 (Ohio App. 1999) 24

Jacobs v. Rosemount Dodge-Winnebago South, 310 N.W.2d 71 (Minn. 1981) 24

MacGillivary v. W. Dana Bartlett Ins. Agency of Lexington, Inc., 436 N.E.2d 964 (Mass. App. 1982) 24

McCoy v. MTI Vacations, Inc., 650 N.E.2d 605 (Ill. App. 1995).....24

TABLE OF AUTHORITIES – Continued

Page

Morgan v. Air Brook Limousine, Inc., 510 A.2d 1197 (N.J. Super. 1986) 24

Pearce v. American Defender Life Ins. Co., 343 S.E.2d 174 (N.C. 1986) 24

Robert's Hawaii School Bus, Inc. v. Laupahoehoe Transp. Co., Inc., 982 P.2d 853 (Haw. 1999) 23

Salois v. Mutual of Omaha Ins. Co., 581 P.2d 1349 (Wash. 1978) 25

State ex rel. Nixon v. Beer Nuts, Ltd., 29 S.W.3d 828 (Mo. App. 2000) 24

William Mushero, Inc. v. Hull, 667 A.2d 853 (Me. 1995) 24

STATUTES

21 U.S.C. § 332 ..... 4, 22

21 U.S.C. § 333 ..... 4, 22

21 U.S.C. § 334 ..... 4, 22

21 U.S.C. § 336 ..... 4, 22

21 U.S.C. § 337 ..... *passim*

21 U.S.C. § 343 ..... 6, 8

21 U.S.C. § 343-1 ..... *passim*

28 U.S.C. § 1257 1

Cal. Bus. and Prof. Code § 17200 8

Cal. Bus. and Prof. Code § 17500 8

TABLE OF AUTHORITIES – Continued

Page

Cal. Civ. Code § 1750 8

Cal. Health & Saf. Code § 110090 8

Cal. Health & Saf. Code § 111840 8

LAW REVIEW ARTICLES AND JOURNALS

Dear & Jessen, *"Followed Rate" and Leading State Cases, 1940-2005*, 41 U.C. Davis L. Rev. 683 (2007) 23

OTHER MATERIALS

58 Fed. Reg. 2457-01 (1993) 26

H.R. Rep. No. 101-538, 2d Sess. (1990) 6, 7

Hearings on S. 1944 (Subcommittee of Committee on Commerce 73d Cong., 2d Sess. (1933)) 4

House Debate on H.R. No. 3562, 101st Cong., 2d Sess., 136 Cong. Rec. 1539 (daily ed. July 30, 1990) 7

OPINIONS BELOW

The opinion of the California Supreme Court (Pet. App. 1) is reported at 42 Cal. 4th 1077, 175 P.3d 1170 (2008). The opinion of the California Court of Appeal (Pet. App. 36) is reported at 142 Cal. App. 4th 805 (2006). The opinion of the trial court (Pet. App. 51) is unreported.

JURISDICTION

The opinion of the California Supreme Court was issued on February 11, 2008. (Pet. App. 1.) The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1257.

STATUTORY PROVISIONS INVOLVED

The FDCA provides, in relevant part:

> (a) Except as provided under subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. . . . .
>
> (b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is

the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1) –

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

21 U.S.C. § 337.

The FDCA further provides, in relevant part:

(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce –

. . . .

(3) any requirement for the labeling of food of the type required by section

> 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title that is not identical to the requirement of such section. . . .

21 U.S.C. § 343-1(a)(3).

STATEMENT OF THE CASE

This case concerns whether FDCA requirements will be enforced exclusively by the federal and state governments, or by private parties as well. When Congress enacted the FDCA in 1938, it deliberately and consciously rejected the possibility of private enforcement in favor of exclusive federal enforcement. When Congress amended the Act in 1990, it carved out a limited exception to exclusive federal enforcement, allowing state governments to enforce certain FDCA violations under specified conditions. Congress, however, never altered its long-standing prohibition against private enforcement actions.

The California Supreme Court nevertheless held that Respondents, private plaintiffs, are entitled to enforce FDCA requirements governing the use of artificial color in farm-raised salmon under identical state laws. Its decision cannot be reconciled with Congress' government enforcement scheme, or with the decisions of this Court and many lower courts reinforcing the Congressional ban on private FDCA enforcement.

A. The Federal Statutory Scheme

1. Congress' Original Plan Mandated Exclusive Federal Enforcement and Unequivocally Prohibited Private Enforcement.

From its inception in 1938, the FDCA was intended to be enforced by the federal government – and not by private parties. In fact, Congress considered and rejected a version of the statute that would have allowed a private right of action. *National Women's Health Network, Inc. v. A. H. Robins Co.*, 545 F. Supp. 1177, 1179-80 (D. Mass. 1982) (citing Hearings on S. 1944 (Subcommittee of Committee on Commerce 73d Cong., 2d Sess. (1933)). It opted instead for a provision mandating that "all" proceedings "for the enforcement, or to restrain violations" of the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337.

In keeping with its plan of exclusive federal enforcement, Congress afforded the Food and Drug Administration ("FDA"), the responsible federal agency, a wide range of enforcement options. It authorized the FDA to bring civil actions to seize misbranded or adulterated goods, to restrain violations of the FDCA, and to seek civil and criminal penalties for such violations. 21 U.S.C. §§ 332-334.

As part of its careful design, Congress also gave the FDA the power *not* to prosecute "minor violations of [the Act] whenever [it] believes that the public interest will be adequately served by a suitable written notice or warning." 21 U.S.C. § 336. Congress

thus ensured that the federal government would decide whether and how to enforce the law.

Courts interpreting the FDCA's enforcement framework before it was amended in 1990 held that Congress had deliberately excluded private claims by placing enforcement exclusively in the hands of the federal government, *see, e.g.*, *Pacific Trading Co. v. Wilson & Co., Inc.*, 547 F.2d 367, 370 (7th Cir. 1976) ("[T]he statute does not provide a cause of action for private parties suing for civil damages."), even those claims brought under state law, *see, e.g.*, *National Women's Health*, 545 F. Supp. at 1181 (holding that a private right of action to enforce FDCA standards is "inconsistent with the federal regulatory scheme, whether the right is based in federal or state law"); *Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278, 283 (D. Mass. 1986) (same).

2. Congress' 1990 Amendments Created A Limited Role For State Governments, But None For Private Parties.

Cognizant of the uniform case law prohibiting private enforcement, Congress enacted the Nutrition Labeling and Education Act of 1990 ("NLEA"), which amended the FDCA to require nutrition labeling on certain foods and to permit state government enforcement of specified labeling requirements. Two provisions of the NLEA pertain to the state enforcement of

federal labeling requirements: sections 343-1 and 337(b).

Section 343-1 allows states to enact laws with requirements "identical" to certain FDCA labeling requirements. 21 U.S.C. § 343-1. One of the FDCA provisions that section 343-1 permits states to replicate is section 343(k), the provision on which Respondents' claims are based, which deems any food containing artificial coloring to be misbranded "unless it bears labeling stating that fact," *id.*, § 343(k). Although section 343-1 is silent on the issue of enforcement, the House Report indicates that state laws enacted pursuant to section 343-1 may only be enforced by "governmental entities":

> The bill . . . contains a provision that would prevent State and local governments from adopting inconsistent requirements with respect to the labeling of nutrients or with respect to the claims that may be made about the nutrients in foods. However, these *governmental entities are explicitly permitted to enforce Federal requirements with respect to nutrition labeling.*

(Pet. App. 74 (H.R. Rep. No. 101-538, 2d Sess., p. 8 (1990) (emphasis added)).)

The other amendment was the addition of section 337(b) to the original section 337 (which was renumbered as section 337(a)). It carved out a narrow exception to exclusive federal enforcement, but only for state governments. Section 337(b) permits state

governments to enforce certain sections of the FDCA in federal court after giving the FDA notice and the opportunity to preempt any state government action with an action of its own. 21 U.S.C. § 337(b).

Together, sections 337(b) and 343-1 were intended to give states the option of enforcing federal labeling requirements under the mantle of federal or state law, in either federal or state court. Under section 337, "[a] State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of" the FDCA in federal court. (21 U.S.C. § 337(b)(1); Pet. App. 75 (H.R. Rep. No. 101-538, 101st Cong., 2d Sess., p. 23 (1990) ("The proceedings [under section 337(b)] would be brought in Federal court and would supplement the FDA's enforcement capabilities.")).) Under section 343-1, states can enforce those same FDCA requirements under identical state law in state court. As Representative Henry Waxman, who originally introduced the bill in the House, explained:

> *H.R. 3562 recognizes the importance of the State role*: by allowing *States* to adopt standards that are identical to the Federal standard, which may be enforced in State court; by allowing the *States* to enforce the Federal standard in Federal court.

(Pet. App. 70 (House Debate on H.R. No. 3562, 101st Cong., 2d Sess., 136 Cong. Rec. 1539 (daily ed. July 30, 1990) (emphasis added)).) By way of both sections 337(b) and 343-1, the NLEA allowed state enforcement of certain federal labeling requirements, but

never granted private parties any enforcement rights whatsoever.

B. Procedural History

Respondents brought this class action claiming that Petitioner supermarkets violated FDCA section 343(k) and its implementing regulations by failing to disclose that farm-raised salmon they sold contained artificial coloring. (JA 162-64 (Consolidated Amended Class Action and Representative Action Complaint ("Complaint")).) Although claims are stated under numerous state laws, including the Unfair Competition Law ("UCL"), Cal. Bus. and Prof. Code § 17200 *et seq.*, the Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code § 1750 *et seq.*, and the False and Misleading Advertising Law, Cal. Bus. and Prof. Code § 17500, the predicate for each claim is identical: the violation of FDA regulations and "equivalent provisions of California law" governing the use of color additives in farm-raised salmon.[1] (JA 169-72 (Complaint).)

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[1] California's UCL proscribes any "unlawful business activity," which includes "anything that can properly be called a business practice and that at the same time is forbidden by law." *Barquis v. Merchants Collection Assn.*, 7 Cal. 3d 94, 113 (1972). Respondents' UCL claims are predicated on violations of the color additive provisions of California's Health and Safety Code – provisions that replicate the FDA's color additive regulations *in toto*, *see* Cal. Health & Saf. Code § 110090. When the California Legislature enacted its "little FDCA," called the Sherman Law, it did not include an express private right of action. *See id.*, § 111840.

Respondents seek restitution, compensatory damages, and an injunction "to permanently halt [Petitioners'] misbranding" in violation of federal and identical state law. (JA 172-73.)

1. The Trial Court's Decision Dismissing Respondents' Case On Federal Preemption Grounds

Petitioners demurred to Respondents' Complaint on federal preemption grounds, arguing that Respondents' claims – all of which are based on violations of the FDCA and its implementing regulations – are barred by the FDCA's express prohibition on private rights of action. (JA 193-241.)

The trial court sustained Petitioners' demurrer and dismissed Respondents' case in its entirety. (Pet. App. 64.) It recognized that Respondents' Complaint does not allege any wrongful conduct beyond the federal violations, and that "[r]esolving [Respondents'] claims will have to turn on [Petitioners'] compliance with the FDA's regulations." (Pet. App. 58.) The trial court concluded that a private state law action that "seeks to borrow FDCA standards is barred by § 337(a) of the FDCA." (Pet. App. 55.)

2. The California Court Of Appeal's Decision Unanimously Affirming The Trial Court's Dismissal On Federal Preemption Grounds

In a published decision, the Court of Appeal unanimously affirmed the trial court's federal preemption decision. (Pet. App. 36.) Relying on this Court's opinion in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Court of Appeal held that FDCA section 337 "precludes a private right of action to enforce the FDCA." (Pet. App. 45.) It reasoned that "[b]y providing that only the federal government and, in some limited circumstances and only after giving notice to the federal government, a state may commence an action to enforce the FDCA, *Congress reserved for the federal government and the states the discretion to enforce or not enforce the FDCA in any particular set of circumstances and afforded the federal government a degree of oversight of the enforcement of the act.*" (Pet. App. 46-47 (emphasis added).)

The Court of Appeal concluded:

> To allow a private person to prosecute a state law private right of action *based on a violation of the FDCA* would interfere with that governmental prosecutorial discretion and federal government oversight and conflict with the clear congressional intent to provide for a comprehensive and exclusive governmental enforcement scheme.

(Pet. App. 47 (original emphasis).) Because all of Respondents' claims are admittedly "based on a violation of the FDCA," the Court of Appeal held that allowing private parties to pursue them would "frustrate the purposes of exclusive federal and state governmental prosecution of the act." (Pet. App. 37-38.) It affirmed the trial court's dismissal on the ground that "section 337(a) impliedly preempts all of [Respondents'] causes of action." (Pet. App. 38.)

3. The California Supreme Court's Decision Allowing Respondents' Private FDCA Claims To Proceed.

The California Supreme Court reversed. (Pet. App. 35.) Its decision begins and ends with the "strong presumption against preemption" (Pet. App. 12, 35), which it applied with "particular force" because consumer protection laws and laws regulating the proper marketing of food "are within the states' historic police powers" (Pet. App. 13).

The court held that Respondents' claims were not preempted because they had sued not under the FDCA itself, but rather under state laws identical to federal standards – laws that FDCA section 343-1 authorized states to enact. (Pet. App. 24.) Acknowledging that Congress "said absolutely nothing" about the private enforcement of such identical state laws (Pet. App. 18), the court nevertheless presumed that Congress "made a conscious choice" not to "preclude

states from providing private remedies for violations of those laws" (Pet. App. 34, 19).

The California Supreme Court further held that section 337 is not a valid source of preemption because Respondents' claims "arise out of violations of [identical state law], not out of the FDCA itself." (Pet. App. 31.) It distinguished, for example, a case in which "the complaint alleged defendant violated the FDCA, misbranded its food in violation of federal regulations, and made actionable health claims in violation of federal regulations." (Pet. App. 32 (discussing *Fraker v. KFC Corp.*, No. 06-CV-01284, 2007 WL 1296571 (S.D. Cal. Apr. 30, 2007)).) The California Supreme Court did not discuss Respondents' allegations that Petitioners violated the FDCA and misbranded their salmon in violation of FDA regulations (JA 163-64) – allegations that serve as the factual predicate for all of their state causes of action (JA 169-72).

REASONS FOR GRANTING THE PETITION

At stake in this case is whether the FDCA will continue to be enforced by government entities – as it has been for seventy years – or whether the door is now open to private class action attorneys to decide whether and how to enforce the federal Act. The California Supreme Court's decision approving Respondents' private FDCA enforcement claims thwarts Congress' exclusively public enforcement plan and

conflicts with this Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4 (2001), which recognizes the Congressional prohibition against private FDCA enforcement actions.

The California Supreme Court's decision is also an open invitation to private plaintiffs nationwide to bring class actions alleging FDCA violations. The decision below will wreck Congress' exclusive government enforcement scheme and all its built-in advantages. Because of the broad jurisprudential and practical significance of the ruling below on federal enforcement of the FDCA, Petitioners respectfully request that this Court obtain and consider the views of the Solicitor General before deciding whether to grant review.

I. THE CALIFORNIA SUPREME COURT'S DECISION CONFLICTS WITH CONGRESS' PROHIBITION AGAINST PRIVATE FDCA ENFORCEMENT ACTIONS AND THIS COURT'S DECISION IN *BUCKMAN* UPHOLDING THAT PROHIBITION.

A. FDCA Section 337 Reflects Congress' Unmistakable Intent To Preclude *All* Private Enforcement Actions, As This Court And Many Lower Courts Have Recognized.

Section 337 of the original FDCA mandated that only the federal government could enforce the Act, 21 U.S.C. § 337(a), and all courts interpreting section

337 before it was amended in 1990 understood that Congress had erected a barrier against private rights of action, whether grounded in federal or state law, *see, e.g.*, *Pacific Trading*, 547 F.2d at 370; *National Women's Health*, 545 F. Supp. at 1181; *Animal Legal Defense Fund*, 626 F. Supp. at 283. When Congress amended section 337 in 1990 to allow certain limited actions by state governments, it was undoubtedly aware of that uniform case law. *Keene Corp. v. United States*, 508 U.S. 200, 212 (1993) (holding that when Congress reenacts statutory language that has been consistently interpreted by the courts, "the presumption that Congress was aware of the[ ] earlier judicial interpretations and, in effect, adopted them" applies). While Congress expressly decided to authorize state enforcement, it made no change in the proscription of private enforcement under section 337. *Bailey v. Johnson*, 48 F.3d 965, 967 n.1 (6th Cir. 1995) (acknowledging, while dismissing a private cause of action to enforce the FDCA, that when Congress amended section 337 in 1990 to allow for certain enforcement actions by state governments, it "made no change respecting private actions").

This Court thus held in 2001 that "[t]he FDCA leaves no doubt" that "private litigants" cannot bring suits for noncompliance with the FDCA. *Buckman*, 531 U.S. at 349 n.4 (citing 21 U.S.C. § 337(a)).[2]

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[2] Federal appellate courts are in accord. *See, e.g.*, *In re Orthopedic Bone Screw Products Liability Litig.*, 193 F.3d 781, 788 (3d Cir. 1999) ("It is well-settled . . . that the FDCA creates

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Although *Buckman*, this Court's only decision addressing section 337, involved state law fraud-on-the-FDA claims that were preempted for reasons largely unique to those claims, numerous lower courts have recognized that Congress' mandate of no private enforcement extends to state law claims to enforce requirements substantively identical to federal law, *see, e.g.*, *Fraker*, 2007 WL 1296571, at *4 ("[T]o the extent Plaintiff contends that alleged violations of the FDCA and [identical California law] give rise to viable state law claims, such claims are impliedly preempted by the FDCA."); *Summit Tech., Inc. v. High-Line Medical Instruments Co.*, 922 F. Supp. 299, 306, 316 (C.D. Cal. 1996) (dismissing state law claims that did not involve "any additional theories" beyond purported FDCA violations as attempts to "circumvent 21 U.S.C. § 337(a)'s denial of a private right of action"); *Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817, 838 (W.D. Tex. 2001) (dismissing on federal preemption grounds state law claims "involv[ing] all the facts and arguments to be determined in a misbranding enforcement action, matters within the sole jurisdiction of the FDA"); *Autin v. Solvay Pharmaceuticals, Inc.*, No. 05-2213, 2006 WL 889423, at *4 (W.D. Tenn. Mar. 31, 2006) (holding that state law claims "based on an alleged violation of

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no private right of action."); *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) (holding that "no . . . private right of action exists" under the FDCA); *Bailey*, 48 F.3d at 968 ("Congress did not intend, either expressly or by implication, to create a private cause of action under the FDCA.").

the FDCA" are preempted by section 337(a)); *Ethex Corp. v. First Horizon Pharmaceutical Corp.*, 228 F. Supp. 2d 1048, 1055 (E.D. Mo. 2002) (dismissing defendant's false advertising counterclaim where the "touchstone" of defendant's argument was an FDCA violation); *Anthony v. Country Life Mfg., L.L.C.*, No. 02C1601, 2002 WL 31269621, at *1 (N.D. Ill. Oct. 9, 2002) (granting defendant's motion to dismiss state consumer fraud claims on the ground that they "amount[ed] to nothing other than an attempt to enforce the FDCA"); *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, No. 96-2459, 1997 WL 94237, at *7 (D. Kan. Feb. 26, 1997) (dismissing plaintiff's unfair competition claim on federal preemption grounds when the "crux" of the claim was an FDCA violation).

Although the California Supreme Court sought to distinguish those cases because "[t]hey invariably deal with a party seeking to enforce (sometimes through the use of state law) the FDCA" (Pet. App. 31), that is no less true here. The factual allegations that support Respondents' state law claims are the very same factual allegations that would support an FDCA claim. (JA 153-173.) As the Court of Appeal recognized, the correct litmus test is not whether claims are labeled state or federal, but "what facts the plaintiffs will be required to prove under the allegations of their complaint":

> If those facts demonstrate violations of the FDCA, then preemption will apply irrespective of the particular state law theories of recovery relied upon by the plaintiffs. To hold

> otherwise would sanction a patent evasion of section 337(a) and would permit the plaintiffs to do the very thing that adherence to federal law would preclude.

(Pet. App. 50.) The California Court of Appeal's decision was but the latest in a long line of cases to hold that state law claims "involv[ing] all the facts and arguments to be determined in a misbranding enforcement action" under the FDCA are preempted. *Healthpoint*, 273 F. Supp. 2d at 838.

The California Supreme Court nevertheless insisted that FDCA section 337 "only implicates efforts to enforce *federal* law," and does not "limit, prohibit, or affect private claims predicated on *state* laws." (Pet. App. 29.)[3] Its opinion ignores the fact that when Congress amended section 337 in 1990, it knew that the provision had been consistently interpreted to preclude private actions brought under *both* federal and identical state law. Had Congress actually intended to allow private state law actions, section 343-1 presented the perfect opportunity. While permitting states to enact laws identical to certain FDCA provisions, Congress easily could have told the courts

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[3] Although not cited by the California Supreme Court, two federal district courts earlier reached the same conclusion. *Vermont Pure Holdings, Ltd. v. Nestle Waters North America, Inc.*, No. Civ.A. 03-11465, 2006 WL 839486, at *6 & n.5 (D. Mass. Mar. 28, 2006); *Reyes v. McDonald's Corp.*, Nos. 06 C 1604, 06 C 2813, 2006 WL 3253579, at *6 (N.D. Ill. Nov. 8, 2006). They are discussed below. (*See* section II, *infra*.)

that – contrary to what they had held – private claims to enforce state replicas of FDCA provisions were to be permissible in the future.

Instead, Congress gave no signal that it intended to authorize private enforcement when it enacted an unambiguous, highly detailed provision for state enforcement. It is hard to believe that Congress legislated about enforcement and only changed the law as to state enforcement, but actually intended to permit both state *and* private enforcement, without mentioning private enforcement at all. *See Monessen Southwestern Ry. Co. v. Morgan*, 486 U.S. 330, 336-38 (1988) (where Congress had amended a statute and "dispensed with [certain] doctrines," but had not addressed the specific doctrine at issue, this Court considered "Congress' silence on this matter in the appropriate historical context" and was "unpersuaded that Congress intended to abrogate that doctrine *sub silentio*"). The NLEA's legislative history, which discusses the "importance of the state role" (Pet. App. 70) and refers to enforcement by "governmental entities" (Pet. App. 74), makes the lower court's theory that Congress somehow intended to allow private enforcement without ever mentioning it even more implausible. Ultimately, it is inconceivable that Congress by its silence changed the law to allow the private enforcement of state laws *identical* to the FDCA – when it had consistently and unequivocally prohibited the private enforcement of the federal law itself.

B. Congress' Longstanding Ban On Private Enforcement Actions Was Unaffected By FDCA Section 343-1.

The California Supreme Court largely justified its decision by pointing to FDCA section 343-1, which not only allows states to adopt laws identical to certain federal labeling requirements, but also in its view permits private parties to enforce those identical state laws. (Pet. App. 27.) Acknowledging that Congress "said absolutely nothing" about private enforcement when it enacted section 343-1 in 1990 (Pet. App. 18), the court nevertheless presumed that Congress "did not intend to alter the status quo, i.e., states may choose to permit their residents to file unfair competition or other claims based on the violation of state laws." (Pet. App. 19.) The court, however, failed to acknowledge that the "status quo" was Congress' longstanding ban on private enforcement actions in FDCA section 337.

In reaching its decision, the California Supreme Court leaned heavily on the "strong presumption against preemption" (Pet. App. 12, 35), which it claimed "applies with particular force here" (Pet. App. 13). While it is true that courts always "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress," *California v. ARC America Corp.*, 490 U.S. 93, 101 (1989) (internal quotations and citation omitted), the court below overlooked the fact that preemption *was* the "clear and manifest purpose of

Congress." Section 337 of the original Act is as plain as enforcement provisions come, commanding that "all" proceedings to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a); *Buckman*, 531 U.S. at 349 n.4. That statutory mandate was born of Congress' decision to reject a version that would have allowed a private right of action, *National Women's Health*, 545 F. Supp. at 1179-80, and was intended to exclude private litigants from the Act's enforcement scheme, *Buckman*, 531 U.S. at 349 n.4.

Thus, when Congress in 1990 allowed states to enact laws identical to the FDCA, it was legislating in an area in which the presumption against preemption had already been overcome by its own more than fifty-year ban on private enforcement. The California Supreme Court's theory that Congress silently obliterated its more than fifty-year-old regime of exclusive government enforcement is untenable. In 1990, Congress intended to allow state *governments* – the same parties that were simultaneously permitted to bring certain enforcement actions in federal court, 21 U.S.C. § 337(b) – to enforce in state court the "little FDCA" provisions that section 343-1 allowed states to enact, but it never intended to allow private enforcement.[4]

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[4] While the court below suggested that this Court's opinions in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) and *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), somehow support its decision (Pet. App. 24-26), those cases have no relevance here.

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The proper construction of this key federal statute should be settled by this Court. *See, e.g., United States v. Donovan*, 429 U.S. 413, 422 (1977) ("We granted certiorari to resolve these issues, which concern the construction of a major federal statute. . . ."); *Reliance Electric Co. v. Emerson Electric Co.*, 404 U.S. 418, 421-22 (1972) (granting certiorari petition "in order to consider an unresolved question under an important federal statute").

II. THE CALIFORNIA SUPREME COURT'S DECISION WILL HAVE PROFOUNDLY NEGATIVE CONSEQUENCES THROUGHOUT THE COUNTRY.

Exclusive government enforcement has always been an integral component of the FDCA. Congress from the start eschewed the idea of private enforcement, *National Women's Health*, 545 F. Supp. at

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Both decisions addressed only whether the challenged state law claims fell within the scope of the express preemption provisions at issue, never addressing the possibility of conflict preemption. Thus, while the lower court was correct to note that in those cases "the high court considered the impact on assertions of federal preemption of provisions similar to section 343-1" (Pet. App. 24), neither case considered other types of preemption, *see Buckman*, 531 U.S. at 352 ("*Medtronic* did not squarely address the question of implied pre-emption."); *Bates*, 544 U.S. at 458 (conc. & dis. opn. of Thomas, J.) ("Because we need only determine the ordinary meaning of [the Federal Insecticide, Fungicide, and Rodenticide Act provision at issue], the majority rightly declines to address respondent's argument that petitioners' claims are subject to other types of pre-emption.").

1179-80, instead giving the FDA a panoply of enforcement options, 21 U.S.C. §§ 332-334. Importantly, Congress also bestowed upon the FDA the authority not to prosecute "minor violations of [the FDCA] whenever [it] believes that the public interest will be adequately served by a suitable written notice or warning." 21 U.S.C. § 336. By allowing the FDA the discretion to distinguish between minor violations and ones worthy of enforcement, Congress anticipated that the government would determine whether and how to enforce the law. *See, e.g., United States v. Sullivan*, 332 U.S. 689, 694 (1948) (noting that FDCA section 336 grants the Secretary of Health and Human Services the ability to decide not to redress "technical infractions of law"); *United States v. Hunter Pharmacy, Inc.*, 213 F. Supp. 323, 324 (S.D.N.Y. 1963) ("The determination of whether a violation is of such a nature as not to require criminal prosecution to vindicate the public interest is entrusted to the judgment of the Secretary.").

Without this Court's intervention, Congress' government enforcement plan and all its inherent benefits will be lost. As the Sixth Circuit recognized in *Bailey v. Johnson*, a private cause of action under the FDCA would jeopardize the "major advantages" of government enforcement, "including expertise, ability to solicit comment from appropriate sources, direct representation of the public interest, and a uniform enforcement policy." 48 F.3d at 968. Under the California Supreme Court's decision, the enforcement of a vital federal statute and identical state statutes will

be left largely in the hands of class action counsel whose expertise is not in the FDCA, who have no ability to solicit comments on an enforcement policy, whose job is to represent private clients and not the public interest, and who have no ability to pursue a unitary enforcement policy.

If the California Supreme Court's decision allowing private enforcement of the FDCA stands, the reaction will be viral. The California Supreme Court is followed more frequently than any other state court, Dear & Jessen, *"Followed Rate" and Leading State Cases, 1940-2005*, 41 U.C. Davis L. Rev. 683, 693 (2007), so its decision is likely to be widely followed. Moreover, California is not the only state that would allow its unfair competition law to bring private class actions for violation of state laws identical to the FDCA. In fact, a violation of federal or state consumer protection-related statutes automatically constitutes a violation of the unfair competition laws of numerous states.[5]

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[5] *See, e.g., Cheshire Mortgage Service, Inc. v. Montes*, 612 A.2d 1130, 1143 (Conn. 1992) (holding that plaintiff's violation of the federal Truth in Lending Act and a Connecticut statute governing prepaid finance charges automatically resulted in violation of the state unfair trade practices act); *Tuckish v. Pompano Motor Co.*, 337 F. Supp. 2d 1313, 1319-20 (S.D. Fla. 2004) (holding that the violation of a Federal Trade Commission Act rule supported a cause of action under Florida's unfair trade practices act); *Ai v. Frank Huff Agency, Ltd.*, 607 P.2d 1304, 1311 (Haw. 1980), overruled on other grounds, *Robert's Hawaii School Bus, Inc. v. Laupahoehoe Transp. Co., Inc.*, 982 P.2d 853 (Haw.

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1999) (holding that a collection agency that failed to comply with state debt collection provisions also violated state's prohibition against unfair trade practices); *McCoy v. MTI Vacations, Inc.*, 650 N.E.2d 605, 607 (Ill. App. 1995) (holding that the state's consumer fraud act provides a private cause of action to persons damaged as a result of violations of Illinois' Travel Promotion Consumer Protection Act); *William Mushero, Inc. v. Hull*, 667 A.2d 853, 855 (Me. 1995) (holding that a violation of the Home Construction Contracts Act also creates liability under the state unfair trade practices act); *MacGillivary v. W. Dana Bartlett Ins. Agency of Lexington, Inc.*, 436 N.E.2d 964, 969 (Mass. App. 1982) (holding that negligent violation of a statute governing unlicensed insurers constituted violation of the state's unfair trade practices law); *Jacobs v. Rosemount Dodge-Winnebago South*, 310 N.W.2d 71, 79 (Minn. 1981) (holding that breach of an express warranty in violation of a Minnesota statute also amounts to violation of the state consumer protection act "[a]s a matter of law"); *State ex rel. Nixon v. Beer Nuts, Ltd.*, 29 S.W.3d 828, 837-38 (Mo. App. 2000) (holding that selling beer in violation of state liquor licensing requirements subjected defendant to liability under the state consumer protection statute); *Chroniak v. Golden Investment Corp.*, 983 F.2d 1140, 1147 (1st Cir. 1993) (holding that a lender's violation of New Hampshire's Second Mortgage Home Loans Act formed a predicate "unfair or deceptive practice or act" under New Hampshire's consumer protection act); *Morgan v. Air Brook Limousine, Inc.*, 510 A.2d 1197, 1205 (N.J. Super. 1986) (holding that a violation of the Federal Trade Commission rule dealing with unfair and deceptive franchising practices "constitutes a per se unconscionable commercial act or practice in violation" of the New Jersey consumer fraud act); *In re Scrimpsher*, 17 B.R. 999, 1015 (Bankr. N.D.N.Y. 1982) (holding that a violation of the federal Fair Debt Collection Practices Act subjected defendant to concurrent liability under the state consumer fraud act); *Pearce v. American Defender Life Ins. Co.*, 343 S.E.2d 174, 180 (N.C. 1986) (holding that insurer's representation in violation of state insurance law "as a matter of law constitutes an unfair or deceptive trade practice" under the state's unfair and deceptive trade practices act); *Ganson v. Vaughn*, 735 N.E.2d 483, 486 (Ohio App. 1999)

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This is not, in short, a problem that will be limited or is unique to California. In fact, federal district courts in Massachusetts and Illinois have already held that FDCA section 343-1 permits private actions under various state unfair competition laws for violation of FDCA requirements. *Vermont Pure Holdings, Ltd. v. Nestle Waters North America*, No. Civ.A. 03-11465, 2006 WL 839486, at *6 & n.5 (D. Mass. Mar. 28, 2006) (holding that plaintiff could pursue claims under the unfair competition laws of at least six different states, including Connecticut, Massachusetts, Maine, New Hampshire, New York, and Rhode Island, for violations of statutes in each of those states incorporating the FDA's definition of the term "spring water"); *Reyes v. McDonald's Corp.*, Nos. 06 C 1604, 06 C 2813, 2006 WL 3253579, at *6 (N.D. Ill. Nov. 8, 2006) (allowing a claim under the state's consumer fraud act "seeking to enforce the exact terms of the NLEA").

The certain flood of private class actions nationwide will undermine federal and state governments' ability to enforce federal labeling requirements

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(holding that failure to comply with an administrative code provision regarding refund policies and deposits in consumer transactions constitutes an automatic violation of the state consumer sales practices act); *Salois v. Mutual of Omaha Ins. Co.*, 581 P.2d 1349, 1350 (Wash. 1978) (holding that insurer's breach of duty of good faith and fair dealing by refusing to pay insured's claim for benefits was unlawful and against public policy and therefore also a violation of the state consumer protection act).

"consistently with [their] judgment and objectives." *Buckman*, 531 U.S. at 350. The federal and state governments can certainly coordinate their enforcement efforts; the FDA has even declared its intent "to work with the States to attempt to ensure that State provisions that are identical to provisions in the act are interpreted by the States in a way that is as consistent as possible with the FDA's interpretation of the Federal provisions." 58 Fed. Reg. 2457-01, 2458 (1993). The FDA, however, cannot possibly work with countless plaintiffs' lawyers across the country to ensure that their class actions are "as consistent as possible with the FDA's interpretation of the Federal provisions." Instead, inconsistent lawsuits and inconsistent judgments will abound, throwing the enforcement of the Act and identical state laws into hopeless confusion.

The adverse impact of the California Supreme Court's decision cannot be overstated. Permitting private parties to enforce the FDCA and identical state statutes will frustrate Congress' intent to keep enforcement in the hands of experienced government entities capable of coordinating their enforcement efforts. If the decision remains, class action litigation concerning alleged violations of the FDCA and identical state statutes will explode nationwide, wrecking an enforcement regime that has remained in place for the last seventy years. Because the California Supreme Court's decision will have such a radical impact on governmental discretion, oversight, and enforcement, Petitioners respectfully request that

this Court call for the views of the Solicitor General in deciding whether review is appropriate.

CONCLUSION

Congress provided for an exclusive government enforcement scheme to avoid inconsistent judgments and to preserve the governmental discretion and oversight that it believed was necessary for the Act's effective enforcement. Had Congress intended to change that deliberate, longstanding regime, it would have clearly said so. The California Supreme Court's unilateral decision to demolish Congress' well-constructed enforcement framework necessitates this Court's review.

Respectfully submitted,

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175 P.3d 1170

Supreme Court of California
FARM RAISED SALMON CASES.
No. S147171.

Feb. 11, 2008.

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MORENO, J.

Plaintiffs filed a class and representative action alleging that various grocery stores violated state law by selling artificially colored farmed salmon without

disclosing to their customers the use of color additives.[1] Defendants successfully demurred in the trial court, arguing the action was preempted by section 337(a) of title 21 of the United States Code, a provision of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 301 et seq.).[2] The Court of Appeal affirmed the resulting judgment of dismissal.

We granted review to decide whether plaintiffs' action was preempted by the FDCA. We conclude that section 337(a) does not preempt the action as plaintiffs do not seek to "enforce[ ], or to restrain violations" of, the FDCA. (§ 337(a).) Rather, plaintiffs' claims for deceptive marketing of food products are predicated on state laws establishing independent state disclosure requirements "identical to" the disclosure requirements imposed by the FDCA, something Congress explicitly approved in section 343-1. (§ 343-1(a)(3).) Accordingly, we reverse the Court of Appeal's judgment and remand the matter to that court for further proceedings consistent with our opinion.

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[1] The grocery stores include Albertson's, Inc., Safeway, Inc., The Kroger Company, Trader Joe's, Costco Wholesale Corp., Whole Foods Market, Inc., Bristol Farms, Inc., Ocean Beauty Seafoods, Inc., and various subsidiary stores owned and operated by these stores (collectively, defendants).

[2] All further unlabeled statutory references are to title 21 of the United States Code.

I. BACKGROUND

A. Facts and Procedural History

Various individuals initiated separate actions against defendants alleging the grocery stores sold artificially colored farmed salmon without disclosing to consumers the use of color additives.[3] The separate actions were coordinated in Judicial Council Coordination Proceeding No. 4329.

In March 2004, plaintiffs filed a coordinated complaint alleging as a class and representative action that fish farmers feed farm-raised salmon the chemicals astaxanthin and canthaxanthin to obtain a color of flesh resembling that of wild salmon.[4] Plaintiffs allege the flesh of farm-raised salmon appears grayish without the chemical additives and that consumers believe the color of salmon is an indication of its origin, quality, freshness, flavor, and other characteristics. Plaintiffs allege that concerns have been raised about the potential health risks of consuming

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[3] The factual and procedural history is largely taken from the Court of Appeal's opinion.

[4] While astaxanthin and canthaxanthin can occur naturally, the color additives used for feeding farmed salmon are manufactured from petrochemicals. (*See* Burros, *Issues of Purity and Pollution Leave Farmed Salmon Looking Less Rosy*, N.Y. Times (May 28, 2003) p. F1.) Salmon farmers can manipulate the flesh color of their product by increasing or decreasing the amount of chemical dye. Indeed, one of the dye manufacturers "offers salmon farmers the SalmoFan, a sort of paint wheel with assorted shades of pink, to help them create the color they think their customers want." (*Ibid.*)

the artificial coloring agents in particular and farm-raised salmon in general. They further allege that parallel federal and state laws require food labeling to state that farmed salmon is artificially colored and defendants failed to comply with those requirements. Plaintiffs also allege the failure to disclose the use of artificial coloring has caused consumers to believe farmed salmon is wild salmon.

The complaint asserts four state law causes of action: (1) violation of the unfair competition law (UCL) (Bus. & Prof.Code, § 17200 et seq.); (2) unfair or deceptive trade practices under the Consumers Legal Remedies Act (CLRA) (Civ.Code, § 1750 et seq.); (3) violation of the false advertising law (Bus. & Prof.Code, § 17500 et seq.); and (4) negligent misrepresentation. The laws alleged to be violated as a predicate for the "unlawful" prong of plaintiffs' UCL claim (*id.*, § 17200) include provisions of the state Sherman Food, Drug, and Cosmetic Law (Health & Saf.Code, § 109875 et seq.) (Sherman Law).[5]

Defendants jointly demurred on several grounds, including that (1) section 337(a)[6] preempts plaintiffs'

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[5] There is no dispute that, under California law, private parties may assert UCL claims based on violations of the Sherman Law. (*Committee on Children's Television, Inc. v. General Foods Corp.* (1983) 35 Cal.3d 197, 210-211, 197 Cal.Rptr. 783, 673 P.2d 660 (*Children's Television*).)

[6] Section 337(a) provides: "Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." Subsection (b) allows states to initiate proceedings in their

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state law claims; (2) further consideration of the complaint could conflict with regulation and enforcement by the United States Food and Drug Administration (FDA) or California's Department of Health Services (DHS), so the action should be dismissed under the primary jurisdiction doctrine; and (3) plaintiffs failed to allege affirmative representation as required in order to state a cause of action under several provisions of the CLRA. Defendants also moved to strike portions of the complaint.

The trial court sustained the demurrer as to each count, with leave to amend. The court held that section 337(a) preempts plaintiffs' state law claims, that the dispute should be referred to the FDA or the DHS under the primary jurisdiction doctrine, and that plaintiffs failed to state a claim for violation of the CLRA because they failed to allege the necessary affirmative representation. Plaintiffs elected not to amend their complaint and instead challenged on appeal the sustaining of the demurrer.

The Court of Appeal affirmed the trial court's finding of preemption, holding that section 337(a) precludes private enforcement of the FDCA, that plaintiffs' state law claims are predicated on a violation of the FDCA, and, therefore, that section 337(a)

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own name in federal court to enforce, or restrain violations of, certain provisions of the FDCA after first giving 30 days' notice to the federal government and allowing the federal government to decide whether it wants to commence an enforcement action.

impliedly preempts plaintiffs' state law claims.[7] In light of its holding, the Court of Appeal did not reach or discuss the other grounds asserted by defendants in support of their demurrer. We granted plaintiffs' petition for review.

B. Relevant Federal and State Laws

1. The FDCA Requires Disclosure of the Use of Color Additives

The FDCA prohibits the misbranding of any food. (§ 331(b).) A food "shall be deemed to be misbranded" under the FDCA if "its labeling is false or misleading in any particular. . . ." (§ 343(a).) More important to this case, a food is also deemed misbranded if "[i]t bears or contains any . . . artificial coloring . . . unless it bears labeling stating that fact. . . ." (§ 343(k).)

FDA regulations permit the use of the chemical substances astaxanthin and canthaxanthin in "the feed of salmonid fish" as color additives "to enhance the pink to orange-red color of the flesh of salmonid fish." (21 C.F.R. §§ 73.35(c) [astaxanthin], 73.75(c)(3) [canthaxanthin] (2007).) If used, however, the chemicals' presence

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[7] The state Attorney General filed an amicus curiae brief addressing defendants' section 337 argument. The brief also directed the Court of Appeal's attention to section 343-1(a)(3) and argued that the statute expressly permits states to enact laws identical to federal requirements governing the labeling of artificially colored food. While the court's opinion acknowledged and addressed the Attorney General's section 337 arguments, it did not address the section 343-1 argument.

must be declared as prescribed by the FDA (*id.*, §§ 73.35(d)(3), 73.75(d)(4)). Use of a color additive must be declared through the use of the phrases "'Artificial Color,' 'Artificial Color Added,' or 'Color Added' (or by an equally informative term that makes clear that a color additive has been used in the food)." (*Id.*, § 101.22(k)(2) (2007).) Alternatively, disclosing the actual color additive used satisfies FDA regulations. (*Ibid.*) The disclosure that a color additive has been used "shall be placed on the food or on its container or wrapper, or on any two or all three of these, as may be necessary to render such statement likely to be read by the ordinary person under customary conditions of purchase and use of such food." (*Id.*, § 101.22(c).)

2. The FDCA Permits States to Establish Identical Requirements

Congress amended the FDCA with the Nutrition Labeling and Education Act of 1990 (NLEA). (Pub.L. No. 101-535 (Nov. 8, 1990) 104 Stat. 2353.) The purpose of the NLEA was to create uniform national standards regarding the labeling of food and to prevent states from adopting inconsistent requirements with respect to the labeling of nutrients. (Remarks of Rep. Waxman, 136 Cong. Rec. 5840 (daily ed. July 30, 1990) [debate on H.R. No. 3562, 101st Cong., 2d Sess.].) To that end, the NLEA included an explicit preemption provision in the form of section 343-1(a) (Pub.L. No. 101-535, § 6 (Nov. 8, 1990) 104 Stat. 2362-2364), which provides that "no State or political

subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce – [¶] . . . [¶] (3) any requirement for the labeling of food of the type required by section . . . 343(k) of this title *that is not identical to the requirement* of such section. . . ." (§ 343-1(a), italics added.)[8]

Although section 343-1 speaks in terms of what states may *not* do, by negative implication, section 343-1 also expresses what states *may* do, i.e., states *may* establish their own requirements pertaining to the labeling of artificially colored food so long as their requirements are identical to those contained in the FDCA in section 343(k). (60 Fed.Reg. 57120 (Nov. 13, 1995) [under FDA regulations, "if the State requirement is identical to Federal law, there is no issue of preemption"]; *Consumer Justice Center v. Olympian Labs, Inc.* (2002) 99 Cal.App.4th 1056, 1065, 121 Cal.Rptr.2d 749 (*Consumer Justice*) ["[s]tates *can* enforce labeling rules which *are* identical" (original italics)]; cf. *Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 495, 116 S.Ct. 2240, 135 L.Ed.2d 700 (*Medtronic*)

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[8] FDA regulations make clear that the phrase "not identical to" in section 343-1(a)(3) "does not refer to the specific words in the requirement." (21 C.F.R. § 100.1(c)(4) (2007).) "[I]f the state requirement does the same thing that the Federal law does, even if the words are not exactly the same, then it is effectively the same requirement as the Federal requirement. . . . [s]uch a State or local requirement is consistent with the Federal requirement." (60 Fed.Reg. 57120 (Nov. 13, 1995).)

[reaching same conclusion regarding similar FDCA preemption provision in section 360k].)

3. The Sherman Law Imposes Requirements "Identical to" Those Contained in Section 343(k)

Like the FDCA, the Sherman Law broadly prohibits the misbranding of food. (Health & Saf.Code, § 110765.) Among various examples of what constitutes misbranded food (*e.g.*, *id.*, § 110660 et seq.), the Sherman Law uses language "identical to" section 343(k) to provide that food is misbranded "if it bears or contains any . . . artificial coloring . . . unless its labeling states that fact." (Health & Saf.Code, § 110740.) The Sherman Law provides that disclosing the addition of "color" will suffice (*id.*, § 110725, subd. (a)) and requires that any disclosure be "prominently placed . . . and in terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." (*Id.*, § 110705.)

Additionally, the Sherman Law incorporates "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the [FDCA]" as "the food labeling regulations of this state." (Health & Saf.Code, § 110100, subd. (a).) Thus, California has adopted as its own the FDA regulations regarding the use of (and disclosure of the use of) astaxanthin and canthaxanthin in the feeding of farmed salmon (*see* 21 C.F.R. §§ 73.35, 73.75 (2007)).

4. Section 337 Specifies Who Has Standing to Enforce the FDCA

Originally enacted in 1938, section 337 is a standing provision, providing that "all such proceedings for the enforcement, or to restrain violations, *of* [*the FDCA*] shall be by and in the name of the United States. . . ."[9] (Act of June 25, 1938, ch. 675, § 307, 52 Stat. 1046, italics added.) Section 337 precludes private enforcement of the FDCA (§ 337(a); *Buckman Co. v. Plaintiffs' Legal Comm.* (2001) 531 U.S. 341, 349, fn. 4, 352, 121 S.Ct. 1012, 148 L.Ed.2d 854 (*Buckman*)) and limits the circumstances under which states may seek to enforce the FDCA in federal court (§ 337(b)). Whether or not section 337 also precludes private claims predicated on state law is the crux of the present litigation and will be discussed at greater length below.

C. Principles of Preemption

As we have previously explained, "[t]he basic rules of preemption are not in dispute: Under the supremacy clause of the United States Constitution (art. VI, cl. 2), Congress has the power to preempt state law concerning matters that lie within the authority of Congress. [Citation.] In determining

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[9] The NLEA relabeled the original section 337 as section 337(a) (Pub.L. No. 101-535, § 4 (Nov. 8, 1990) 104 Stat. 2362) and added subsection (b). (§ 337(b); *see ante*, 72 Cal.Rptr.3d at pp. 116-117, fn. 6, 175 P.3d at p. 1174, fn. 6.)

whether federal law preempts state law, a court's task is to discern congressional intent. [Citation.] Congress's express intent in this regard will be found when Congress explicitly states that it is preempting state authority. [Citation.] Congress's implied intent to preempt is found (i) when it is clear that Congress intended, by comprehensive legislation, to occupy the entire field of regulation, leaving no room for the states to supplement federal law [citation]; (ii) when compliance with both federal and state regulations is an impossibility [citation]; or (iii) when state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' [Citations.]" (*Bronco Wine Co. v. Jolly* (2004) 33 Cal.4th 943, 955, 17 Cal.Rptr.3d 180, 95 P.3d 422 (*Bronco Wine*); *Viva! International Voice for Animals v. Adidas Promotional Retail Operations, Inc.* (2007) 41 Cal.4th 929, 935-936, 63 Cal.Rptr.3d 50, 162 P.3d 569 (*Viva! International*).) It is well established that the party who asserts that a state law is preempted bears the burden of so demonstrating. (*Viva! International, supra,* 41 Cal.4th at p. 936, 63 Cal.Rptr.3d 50, 162 P.3d 569; *Bronco Wine, supra,* 33 Cal.4th at p. 956, 17 Cal.Rptr.3d 180, 95 P.3d 422.)

The interpretation of the federal law at issue here is further informed by a strong presumption against preemption. (*See Medtronic, supra,* 518 U.S. at p. 485, 116 S.Ct. 2240; *see also Viva! International, supra,* 41 Cal.4th at p. 938, 63 Cal.Rptr.3d 50, 162 P.3d 569; *Bronco Wine, supra,* 33 Cal.4th at p. 974, 17 Cal.Rptr.3d 180, 95 P.3d 422.) "[B]ecause the States

are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state law causes of action. In all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' [citation] we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.' [Citations.]" (*Medtronic, supra,* 518 U.S. at p. 485, 116 S.Ct. 2240; *Bates v. Dow Agrosciences LLC* (2005) 544 U.S. 431, 449, 125 S.Ct. 1788, 161 L.Ed.2d 687 (*Bates*); *Big Creek Lumber Co. v. County of Santa Cruz* (2006) 38 Cal.4th 1139, 1150, fn. 7, 45 Cal.Rptr.3d 21, 136 P.3d 821.) We apply this presumption to the *existence* as well as the *scope* of preemption. (*Medtronic, supra,* 518 U.S. at p. 485, 116 S.Ct. 2240.)

There can be no doubt that the presumption applies with particular force here. (*See Bronco Wine, supra,* 33 Cal.4th at p. 974, 17 Cal.Rptr.3d 180, 95 P.3d 422.) As the Court of Appeal acknowledged here, "[c]onsumer protection laws such as the [UCL], false advertising law, and CLRA, are within the states' historic police powers and therefore are subject to the presumption against preemption." Laws regulating the proper marketing of food, including the prevention of deceptive sales practices, are likewise within states' historic police powers. (*Florida Lime & Avocado Growers v. Paul* (1963) 373 U.S. 132, 144, 83 S.Ct. 1210, 10 L.Ed.2d 248; *Bronco Wine, supra,* 33

Cal.4th at pp. 959-961, 17 Cal.Rptr.3d 180, 95 P.3d 422 [describing history of state regulation].) Indeed, as early as the 1860's, California was enacting laws regulating food marketing. (*See, e.g.*, Stats. 1862, ch. 365, pp. 484-485 [prohibiting sale of adulterated and misbranded food]; *Bronco Wine, supra,* 33 Cal.4th at pp. 961-963, 17 Cal.Rptr.3d 180, 95 P.3d 422.)

It is with these principles in mind that we consider whether it was the "'clear and manifest purpose'" of Congress (*Medtronic, supra,* 518 U.S. at p. 485, 116 S.Ct. 2240) to preclude states from providing private remedies for the violations of the state statutes at issue here.

II. DISCUSSION

We begin by noting the type of preemption defendants assert here.[10] As the Court of Appeal concluded, it is clear that Congress has not expressly preempted private claims predicated on *state laws* imposing requirements identical to those contained in the FDCA (*see* §§ 337, 343-1), and defendants do not claim otherwise. Neither do defendants contend that plaintiffs' action is impliedly preempted as a result of Congress occupying the field. Nor do defendants

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[10] We apply a de novo standard of review because this case was resolved on demurrer (*McCall v. PacifiCare of Cal., Inc.* (2001) 25 Cal.4th 412, 415, 106 Cal.Rptr.2d 271, 21 P.3d 1189) and because federal preemption presents a pure question of law (*Spielholz v. Superior Court* (2001) 86 Cal.App.4th 1366, 1371, 104 Cal.Rptr.2d 197).

argue the action is preempted because compliance with both state and federal laws is impossible – as state and federal laws impose identical requirements regarding the disclosure of the use of artificial coloring, compliance with one necessarily ensures compliance with the other. (*Compare*, *e.g.*, § 343(k) with Health & Saf.Code, § 110740.) Instead, defendants assert plaintiffs' claims are impliedly preempted because they stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

The Court of Appeal concluded that plaintiffs' action was indeed impliedly preempted, basing its holding solely on its reading and application of section 337(a). While the Court of Appeal acknowledged that the statute's plain language limits its scope to efforts that seek to enforce the FDCA itself, it nonetheless concluded that section 337(a) also operates to preempt plaintiffs' purely state law claims. The Court of Appeal reasoned that, because section 337(a) explicitly bars the private enforcement of FDCA provisions (*Buckman, supra,* 531 U.S. at pp. 349, fn. 4, 352, 121 S.Ct. 1012), section 337(a) must therefore also impliedly bar private claims predicated on state provisions imposing requirements identical to those contained in the FDCA. However plausible the Court of Appeal's reasoning may appear when section 337(a) is considered in isolation, its reasoning is seriously undermined when section 343-1 is taken

into account.[11] Accordingly, we begin with a discussion of that statute.

As previously mentioned (*ante,* 72 Cal.Rptr.3d at p. 117, fn. 7, 175 P.3d at p. 1174, fn. 7), the Attorney General filed an amicus curiae brief in the lower court in which it discussed the impact of section 343-1 at length. Defendants filed an answer fully responding to the argument. After the Court of Appeal issued its opinion without discussing the statute, the Attorney General filed a letter in support of plaintiffs' petition for review in which it again addressed the provision. Defendants addressed the argument in their response letter. In neither their answer to the amicus curiae brief nor their response to the Attorney General's letter did defendants assert that section 343-1 had not been properly raised. Plaintiffs then discussed section 343-1 in their opening brief in this court and defendants fully briefed the issue while simultaneously arguing plaintiffs should not be allowed to raise it. Accordingly, all the parties have had a reasonable opportunity to brief this issue and we may properly consider it. (Cal. Rules of Court, rule 8.516(b)(2).)

Additionally, while plaintiffs' petition for review did not explicitly cite section 343-1, it did broadly

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[11] Defendants ask this court to ignore section 343-1 when considering Congress's intent, contending plaintiffs have not properly raised the statute and implying the Court of Appeal was not given an opportunity to consider the issue. We disagree and decline defendants' invitation to disregard section 343-1.

raise the issue of "whether the FDCA preempts parallel state law requirements." Because our central task in preemption analysis is to discern Congress's intent (*Bronco Wine, supra,* 33 Cal.4th at p. 955, 17 Cal.Rptr.3d 180, 95 P.3d 422), it is appropriate to discuss a pertinent FDCA provision shedding light on that intent.

Moreover, the impact of section 343-1 presents a purely legal issue and does not require the further development of a factual record. We have previously allowed parties to "'advance new theories on appeal when the issue posed is purely a question of law based on undisputed facts, and involves important questions of public policy.'" (*Cedars-Sinai Medical Center v. Superior Court* (1998) 18 Cal.4th 1, 6, 74 Cal.Rptr.2d 248, 954 P.2d 511.)

A. Section 343-1 Permits States to Adopt Identical Requirements

The words of section 343-1 clearly and unmistakably evince Congress's intent to authorize states to establish laws that are "identical to" federal law. (§ 343-1; *Consumer Justice, supra,* 99 Cal.App.4th at p. 1065, 121 Cal.Rptr.2d 749.) That is precisely what California did in enacting the Sherman Law. The Sherman Law provision prohibiting misbranding with regard to the use of color additives (Health & Saf.Code, § 110740) is identical to section 343(k), the parallel federal requirement specifically listed in section 343-1 as one of the federal statutes covered by

the express preemption provision. Additionally, the Sherman Law incorporates all of the food labeling regulations promulgated by the FDA (Health & Saf.Code, § 110100, subd. (a)), including those having to do with the use of astaxanthin and canthaxanthin in the feeding of farmed salmon (21 C.F.R. §§ 73.35, 73.75 (2007)). Accordingly, the state requirements at issue here are explicitly permitted by section 343-1. (*See Consumer Justice, supra,* 99 Cal.App.4th at p. 1065, 121 Cal.Rptr.2d 749 ["[s]tates *can* enforce labeling rules which *are* identical" (original italics)].)

While Congress clearly stated its intent to allow states to establish their own identical laws, it said absolutely nothing about proscribing the range of available remedies states might choose to provide for the violation of those laws, such as private actions. Nor is there anything in the legislative history suggesting that any proponent of the legislation intended a sweeping preemption of private actions predicated on requirements contained in state laws. Defendants cite portions of the legislative history for that proposition, but the cited excerpts actually bolster our conclusion. For example, defendants point to the remarks of Representative Henry Waxman, who originally introduced the NLEA in the House of Representatives: "[The NLEA] recognizes the importance of the State role: by allowing *States* to adopt standards that are identical to the Federal standard, which may be enforced in State court; by allowing the *States* to enforce the Federal standard in Federal

court." (Remarks of Rep. Waxman, 136 Cong. Rec. 1539 (daily ed. July 30, 1990), italics added.)

Far from establishing that Congress intended to preclude private claims based on state laws, Representative Waxman's remarks suggest the opposite. By explicitly stating that the NLEA would allow states to enforce the federal requirements in federal court, but not discussing who would be allowed to enforce the identical state requirements, the remarks suggest that Congress did not intend to alter the status quo, i.e., states may choose to permit their residents to file unfair competition or other claims based on the violation of state laws (*see, e.g., Children's Television, supra,* 35 Cal.3d at pp. 210-211, 197 Cal.Rptr. 783, 673 P.2d 660).[12] If Congress intended to permit states to enact identical laws on the one hand, but preclude states from providing private remedies for violations of those laws on the other hand, "its failure even to hint at it is spectacularly odd." (*Medtronic, supra,* 518 U.S. at p. 491, 116 S.Ct. 2240 (plur. opn. of Stevens, J.).) Congressional silence on this point is all the

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[12] Indeed, the NLEA was enacted in 1990 primarily to establish a national uniform labeling standard in place of the patchwork of different state standards that existed at the time. Under defendants' interpretation of the FDCA, private claims based on those pre-NLEA state labeling laws would have been permitted (since they were presumably different from the FDCA), but Congress's adoption of a uniform standard in the form of the NLEA had the effect of eliminating private causes of action based on state labeling laws. It is hard to believe that Congress would have intended such a result without saying so.

more strange in light of Congress's presumed awareness that "virtually every state in the nation permits one or more nongovernmental parties to enforce state . . . laws of general applicability prohibiting deceptive or unfair acts and practices in the marketplace." (Annot., Right to Private Action Under State Consumer Protection Act – Preconditions to Action (2004) 117 A.L.R.5th 155.)[13]

Further undermining defendants' interpretation is the fact that Congress made clear that the preemptive scope of section 343-1 was to sweep no further than the plain language of the statute itself. In NLEA section 6(c)(1) (an uncodified provision), Congress provided that "[t]he [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [section 343-1] of the [FDCA]." (Pub.L. No. 101-535, § 6(c)(1) (Nov. 8, 1990), 104 Stat. 2364.) Thus, Congress's decision not to expressly supplant private claims based on those state laws authorized by section 343-1 should be interpreted as its considered decision to continue to allow states to provide such private remedies.

The language of this uncodified provision is significant for two additional reasons. First, it evidences an intent to allow state and federal regulation

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[13] For example, we held in *Children's Television, supra,* 35 Cal.3d at pages 210, 197 Cal.Rptr. 783, 673 P.2d 660 to 211, that, in California, "any unlawful business practice, *including violations of the Sherman law,* may be redressed by a [UCL] private action." (Italics added.)

to co-exist. "Where Congress establishes a regime of dual state-federal regulation, 'conflict-preemption analysis must be applied sensitively . . . so as to prevent the diminution of the role Congress reserved to the States while at the same time preserving the federal role.' [Citations.]"[14] (*Viva! International, supra,* 41 Cal.4th at p. 942, 63 Cal.Rptr.3d 50, 162 P.3d 569.) Defendants' interpretation would substantially interfere with state legal remedies, "producing a serious intrusion into state sovereignty while simultaneously wiping out the possibility of remedy for the [plaintiffs'] alleged injuries." (*Medtronic, supra,* 518 U.S. at pp. 488-489, 116 S.Ct. 2240 (plur. opn. of Stevens, J.).)

Second, the provision's language is significant because it informs our analysis of the existence of any implied preemption. "[A]n express definition of the pre-emptive reach of a statute 'implies' – *i.e.,* supports a reasonable inference – that Congress did not intend to pre-empt other matters. . . ." (*Freightliner Corp. v. Myrick* (1995) 514 U.S. 280, 288, 115 S.Ct. 1483, 131 L.Ed.2d 385.) While an express clause does not foreclose an inquiry into implied conflict preemption in all cases (*Geier v. American Honda Motor Co., Inc.*

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[14] Indeed, during debate on the NLEA, Congress recognized the important role states' laws have in consumer protection. "The States have played an invaluable role by enforcing State food labeling and advertising laws at a time when consumers have been bombarded with health claims." (H.R.Rep. No. 101-980, 2d Sess., p. 19 (Nov. 14, 1990); *see* remarks of Rep. Waxman, 136 Cong. Rec. 5840 (daily ed. July 30, 1990).)

(2000) 529 U.S. 861, 869, 120 S.Ct. 1913, 146 L.Ed.2d 914), deference should be paid to Congress's detailed attempt to clearly define the scope of preemption under the FDCA. (*See Viva! International, supra,* 41 Cal.4th at p. 945, 63 Cal.Rptr.3d 50, 162 P.3d 569 ["Congress has expressly identified the scope of the state law it intends to preempt; hence, we infer Congress intended to preempt no more than that absent sound contrary evidence."].)

Various provisions of the FDCA clearly demonstrate that "Congress knows how to write a preemption clause" when it wants to (*Consumer Justice, supra,* 99 Cal.App.4th at p. 1059, 121 Cal.Rptr.2d 749) and that "the [FDCA] evidences, far from implied preemption, an instance of implied *non* preemption." (*Id.* at p. 1063, 121 Cal.Rptr.2d 749.) Congress enacted numerous specific express preemption provisions in the FDCA. (*See, e.g.*, §§ 360k (medical devices), 360ss (radiation emissions), 379r (nonprescription drugs), 379s (cosmetics).) The inference to be drawn from these provisions is that Congress, in light of the history of dual state-federal cooperation in this area, did not intend to limit states' options in a broad fashion. Indeed, the preemption provision at issue here, section 343-1, demonstrates Congress's care in deciding what to preempt and what to allow. Section 343-1 is notable both for the number of misbranding provisions it deals with (approximately 20) and for

the detailed nature of its preemptive scope.[15] The language of section 343-1 and the NLEA's express preemption provision is further evidence that Congress chose carefully the manner with which it preempted certain state labeling laws. Defendants have not provided sufficient evidence to contradict the inference that Congress intended a narrow interpretation of the scope of preemption.

In support of their argument that, notwithstanding section 343-1, plaintiffs' action is preempted by section 337, defendants point to NLEA section 6(c)(3) (an uncodified provision) (Pub.L. No. 101-535, § 6(c)(3) (Nov. 8, 1990), 104 Stat. 2364). That provision states that section 343-1 "shall not be construed to affect preemption, express or implied, of *any such requirement* of a State or political subdivision, which may arise under the Constitution, any provision of the [FDCA] not amended by section [343-1], or . . . any Federal regulation, order, or other final agency action. . . ." (Pub.L. No. 101-535, § 6(c)(3) (Nov. 8, 1990), 104 Stat. 2364, italics added.)

This provision is inapplicable to this case for two reasons. First, the phrase "any such requirement" in NLEA section 6(c)(3) refers to the "requirement" discussed in NLEA section 6(c)(2) (Pub.L. No. 101-535,

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[15] The statute, for example, does not apply to requirements governing maple syrup. (Gold, *Legal Strategies to Address the Misrepresentation of Vermont Maple Syrup* (2004) 59 Food & Drug L.J. 93, 103 & fn. 78.)

§ 6(c)(2) (Nov. 8, 1990), 104 Stat. 2364). In NLEA section 6(c)(2), Congress provided that section 343-1 does not apply "to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food. . . ." (Pub.L. No. 101-535, § 6(c)(2) (Nov. 8, 1990), 104 Stat. 2364.) Thus, read in context, it is clear that the phrase "any such requirement" in NLEA section 6(c)(3) refers to the food safety labeling requirement discussed in the immediately preceding provision, NLEA section 6(c)(2). Second, it is undisputed that section 337 bars private enforcement of the FDCA – no one contends section 343-1 alters that conclusion. However, plaintiffs do not seek to enforce the FDCA. Their action is based on the violation of *state law* – albeit state law that is, in compliance with section 343-1, identical to FDCA provisions. Concluding that section 343-1 permits private claims based on state law does not affect section 337' s preemption of efforts to enforce the FDCA.

In *Medtronic, supra,* 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700, and *Bates, supra,* 544 U.S. 431, 125 S.Ct. 1788, 161 L.Ed.2d 687, the high court considered the impact on assertions of federal preemption of provisions similar to section 343-1. In both cases the defendants claimed private suits to enforce state laws identical to federal laws were preempted by federal law. And, in both cases, the high court disagreed.

In *Medtronic, supra,* 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700, the plaintiffs filed a private

state law negligence action against the manufacturer of an allegedly defective pacemaker. The defendants argued that the plaintiffs' action was preempted by the FDCA, as amended by the Medical Device Amendments of 1976 (MDA) (Pub.L. No. 94-295 (May 28, 1976) 90 Stat. 539). (*Medtronic, supra,* 518 U.S. at p. 474, 116 S.Ct. 2240.) The high court, relying on a preemption provision contained in the MDA (§ 360k), disagreed and held that the action was not pre-empted.

Like section 343-1, section 360k provides, "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement – [¶] (1) which is different from, or in addition to, any requirement applicable under this chapter to the device. . . ." (§ 360k(a); *see Medtronic, supra,* 518 U.S. at pp. 481-482, 116 S.Ct. 2240.) Interpreting this provision, the high court concluded that Congress did not intend to preempt "state rules that merely duplicate some or all of [the] federal requirements." (*Medtronic, supra,* at p. 492, 116 S.Ct. 2240.) The high court further reasoned that because Congress authorized states to adopt identical requirements, states were also free to provide for private remedies for violations of those requirements. "[I]t is clear that the [plaintiffs'] allegations may include claims that Medtronic has, to the extent that they exist, violated FDA regulations. At least these claims, [the plaintiffs] suggest, can be maintained without being pre-empted by § 360k, and we agree. [¶] Nothing in § 360k denies [a state] the

right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." (*Medtronic, supra,* 518 U.S. at p. 495, 116 S.Ct. 2240).

In *Bates, supra,* 544 U.S. 431, 125 S.Ct. 1788, 161 L.Ed.2d 687, the high court considered whether plaintiffs' private state law action was preempted by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. § 136 et seq.). The plaintiffs there were Texas peanut farmers who alleged that their crops had been severely damaged by the application of the defendant's pesticide, which had been conditionally registered by the Environmental Protection Agency. (*Bates, supra,* 544 U.S. at p. 435, 125 S.Ct. 1788.) The defendant argued FIFRA preempted the plaintiffs' action. (*Ibid.*)

Like the provision at issue in *Medtronic,* FIFRA contains a preemption provision similar to section 343-1, which provides that states "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter" (7 U.S.C. § 136v(b); *see Bates, supra,* 544 U.S. at p. 436, 125 S.Ct. 1788). The *Bates* court held that "[t]he imposition of state sanctions for violating state rules that merely duplicate federal requirements is equally consistent with the text of [7 U.S.C.] § 136v." (*Bates, supra,* 544 U.S. at p. 442, 125 S.Ct. 1788.) Additionally, although FIFRA did not provide a federal remedy to the farmers, the high court concluded that "nothing in [7 U.S.C.] § 136v(b) precludes States from providing

such a remedy." (*Bates, supra,* 544 U.S. at p. 448, 125 S.Ct. 1788.)

Accordingly, in light of the plain statutory language of section 343-1, and the high court's construction of similar preemption language, we conclude that Congress intended to allow states to establish their own requirements so long as they are identical to those contained in section 343(k), which California has done in the form of the Sherman Law. We further conclude that nothing in the text of section 343-1 or its legislative history supports the assertion that Congress intended to limit the scope of remedies states might choose to provide for the violations of those state laws. We therefore turn to a consideration of whether, notwithstanding section 343-1, section 337 provides a basis for the implied preemption of plaintiffs' claims.

B. Section 337 Does Not Impliedly Preempt Plaintiffs' State Claims

To briefly recap, section 337 is the FDCA standing provision. Section 337(a) provides that, except as set forth in section 337(b), "all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." Section 337(b) allows states to initiate proceedings in their own name in federal court to enforce, or restrain violations of, certain provisions of the FDCA. However, before so doing, a state must give 30 days' notice to the federal government. (§ 337(b).) The federal

government may then decide whether it wants to commence an enforcement action in court and, if it does, the state is precluded from acting to enforce the FDCA. (*Ibid.*)

The crux of defendants' preemption argument is that plaintiffs' private state claims are precluded because they improperly seek to enforce the FDCA in violation of section 337(a). Defendants' starting assumption is incorrect. Plaintiffs do not seek to enforce the FDCA; rather, their deceptive marketing claims are predicated on violations of obligations imposed by the Sherman Law, something that state law undisputedly allows (*Children's Television, supra,* 35 Cal.3d at pp. 210-211, 197 Cal.Rptr. 783, 673 P.2d 660; *cf. Stop Youth Addiction, Inc. v. Lucky Stores, Inc.* (1998) 17 Cal.4th 553, 562-563, 71 Cal.Rptr.2d 731, 950 P.2d 1086). That the Sherman Law imposes obligations identical to those imposed by the FDCA, as it must under section 343-1, does not substantively transform plaintiffs' action into one seeking to enforce federal law. Rather, it merely reflects Congress's considered judgment that states should uniformly regulate food labeling using identical standards. Indeed, while the high court in *Medtronic* did not expressly consider the impact of section 337 on the private state action at issue there, it held that those plaintiffs' private actions were permitted *because* they were identical to the FDCA. (*Medtronic, supra,* 518 U.S. at p. 495, 116 S.Ct. 2240.) It is difficult to believe the high court would have so held if section 337 expressed a "clear and manifest" intent (*Medtronic,* at

p. 485, 116 S.Ct. 2240) to preclude private actions based on state laws explicitly authorized by the FDCA in section 343-1.

Section 337 does not apply to the state law claims presented here. The statute, by its very terms, only implicates efforts to enforce *federal* law. What section 337 does *not* do is limit, prohibit, or affect private claims predicated on *state* laws. (*See Consumer Justice, supra,* 99 Cal.App.4th at p. 1067, fn. 17, 121 Cal.Rptr.2d 749 ["The underlying assumption [in the defendants' briefing] is that this lawsuit is somehow an attempt to use state unfair competition laws to enforce *federal* laws. No, the lawsuit is about state unfair advertising laws."].)[16] The FDA has opined that because "[section 337] applies only to proceedings to enforce the [FDCA]" (58 Fed.Reg. 2458 (Jan. 6, 1993)), "[n]othing in [section 337] would preclude a State from taking action against a particular food under *its own State law*. . . ."[17] (58 Fed.Reg. 2458,

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[16] Defendants claim *Consumer Justice* is distinguishable. They reason that section 337 was not implicated in that case because the plaintiffs' false advertising claims there did not raise an issue "committed to the FDA," and could not "be properly characterized as an attempt to circumvent the [FDCA's] express prohibition on private causes of action . . . " (*Consumer Justice, supra,* 99 Cal.App.4th at p. 1064, 121 Cal.Rptr.2d 749). However, the same is true of plaintiffs' state law claims here. Rather than raising issues "committed to the FDA," plaintiffs' claims arise under laws that section 343-1 explicitly authorizes states to enact.

[17] We note that, as the FDA is the federal agency that Congress has authorized to implement and enforce the FDCA

(Continued on following page)

italics added.) Nor does section 337 affect the ability of states to provide a private remedy for violations of their laws if they so choose.[18] One treatise has noted that "[p]laintiffs may sue under state unfair trade practice laws for omissions that would fit under either FDA or state trade laws. [Fn. omitted.]" (2 O'Reilly, Food and Drug Administration (3d ed.2007) § 26:32, p. 26-43; *see Children's Television, supra,* 35 Cal.3d at pp. 210-211, 197 Cal.Rptr. 783, 673 P.2d 660.)

No court, particularly after passage of the NLEA, has ever held that states may not provide a private remedy for the violation of state laws imposing requirements identical to those imposed by federal law. The cases defendants cite are inapposite, all dealing with efforts to use state laws to directly enforce the FDCA itself. For example, defendants cite *Summit Tech., Inc. v. High-Line Medical Instruments, Co.* (C.D.Cal.1996) 933 F.Supp. 918. However, in that case, the district court allowed the plaintiffs UCL

(§ 371), the FDA is "uniquely qualified to determine whether a particular form of state law . . . should be pre-empted." (*Medtronic, supra,* 518 U.S. at p. 496, 116 S.Ct. 2240; *see Thompson v. Western States Medical Center* (2002) 535 U.S. 357, 362, 122 S.Ct. 1497, 152 L.Ed.2d 563.)

[18] In their briefs, the parties discuss an unpublished federal district court opinion which came to the same conclusion when considering nearly identical facts. (*Vermont Pure Holdings, Ltd. v. Nestle Waters North America, Inc.* (D.Mass., Mar. 28, 2006, No. Civ.A.03-11465) 2006 WL 839486, *6, fn. 3.) Citing unpublished *federal* opinions does not violate our rules. (Cal. Rules of Court, rule 8.1115.) We find the court's reasoning persuasive.

claim to proceed, acknowledging that "under [the UCL], Plaintiff may redress violations of the California Sherman Act. . . ." (*Summit Tech., supra,* 933 F.Supp. at p. 943.) Defendants rely heavily on a footnote in the decision stating, "This is true unless federal law preempts such an action. Thus, a Plaintiff may not bring a [UCL] claim that is, in fact, an attempt to state a claim under the FDCA." (*Summit Tech., supra,* 933 F.Supp. at p. 943, fn. 21.) However, as previously explained, plaintiffs' claims arise out of violations of the Sherman Law, not out of the FDCA itself.

The other cases cited by defendants are similarly unavailing. They invariably deal with a party seeking to enforce (sometimes through the use of state law) the FDCA. The cases are also notable for what they do not address – none involve state laws explicitly authorized by section 343-1 or a similar statute. For example, in *Pediamed Pharms., Inc. v. Breckenridge Pharm., Inc.* (D.Md.2006) 419 F.Supp.2d 715, a pharmaceutical company sued its competitor over the marketing and sale of drugs. The defendant company asserted a state-law unclean hands defense, arguing that the plaintiffs' drugs were being marketed in violation of the FDCA. The district court rejected the defense, reasoning that, "[b]ecause [the defense] requires direct application of the FDCA, which only the FDA is entitled to enforce, these arguments are precluded." (*Pediamed Pharms., Inc. v. Breckenridge Pharm., Inc., supra,* 419 F.Supp.2d at p. 727.)

Defendants cite *Fraker v. KFC Corp.* (S.D.Cal., Apr. 30, 2007, No. 06-CV-01284) 2007 WL 1296571 in their supplemental brief, arguing it is a recent example of a court reaching this issue. However, as with the previous cases, *Fraker* is inapplicable. The plaintiff in *Fraker* brought state law claims against KFC Corporation (formerly Kentucky Fried Chicken) alleging that the defendant misrepresented its product as healthy when it was in fact high in "trans" fat content. (*Id.*, at p. *1.) In dismissing the plaintiff's claims as preempted, the district court noted that the complaint alleged defendant violated the FDCA, misbranded its food in violation of federal regulations, and made actionable health claims in violation of federal regulations. (*Fraker v. KFC Corp., supra,* 2007 WL 1296571 at p. *3.) Accordingly, the court concluded that the state law claims were impermissibly founded on violations of the FDCA and were thus preempted by section 337. (*Fraker v. KFC Corp., supra,* 2007 WL 1296571 at pp. *3-4.)

All of these cases rejected claims or defenses because they were based on violations of the FDCA itself.[19] The district courts reasoned that directly applying the FDCA, as would have been required,

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[19] At oral argument, defendants' counsel cited *Bailey v. Johnson* (6th Cir.1995) 48 F.3d 965. However, for the same reasons as discussed above, *Bailey* is unlike the case presented here. The plaintiffs in *Bailey* argued that "the FDCA created a private, federal right of action." (*Bailey v. Johnson, supra,* 48 F.3d at p. 966.) Plaintiffs here make no such claim.

would run afoul of section 337. By contrast, plaintiffs' claims in this case do not require referring to, or applying, the FDCA. Plaintiffs' claims are based on violation of the Sherman Law and can be resolved with reference to state law alone. Additionally, none of these cited cases considered the impact of section 343-1. Given that section 343-1 explicitly authorizes the enactment of identical state labeling laws, that provision is an important distinction between the cases defendants cite and the one presented here. In short, defendants have not identified any case law to support their argument that Congress clearly and manifestly intended to impliedly preempt with section 337 what it explicitly authorized with section 343-1.

We note also that, as in *Medtronic,* the implication of defendants "sweeping interpretation" would interfere greatly with state legal remedies, "producing a serious intrusion into state sovereignty. . . ." (*Medtronic, supra,* 518 U.S. at p. 488, 116 S.Ct. 2240 (plur. opn. of Stevens, J.).) Defendants argue that the identical requirements contained in the Sherman Law may only be enforced by the state itself, and may not be the basis of private claims. However, if section 337(a)'s explicit preclusion of private enforcement of the FDCA impliedly preempts private claims based on identical state laws, as defendants argue, then it necessarily follows that section 337(b)'s explicit conditions on state enforcement of the FDCA in federal court must also impliedly limit states' enforcement of their own laws in state court. It cannot

be the case that states must give the federal government 30 days notice before seeking to enforce their own laws in state court (as section 337(b) requires when states seek to enforce the FDCA in federal court) and defendants do not argue otherwise.

Defendants assert that allowing private claims based on identical laws in state court would render section 337 meaningless because states would be required to give the FDA notice before initiating actions but private parties would not. This argument misunderstands the scope of section 337 and conflates efforts to enforce federal law with efforts based on state law. As previously discussed, section 337 is only concerned with enforcement of *federal law, i.e.*, the FDCA. If a state brings an action to enforce the FDCA in federal court, it must first notify the FDA under section 337(b). On the other hand, defendants concede that states may enforce their own laws in state court without notifying the FDA at all, even though the laws impose requirements identical to those contained in the FDCA. Defendants identify no persuasive rationale to explain why private claims based on these same state laws would be of any greater concern to Congress than California's enforcement of state laws – in both instances, state laws identical to the FDCA are enforced without first notifying the FDA.

In conclusion, while allowing private remedies based on violations of state laws identical to the FDCA may arguably result in actions that the FDA itself might not have pursued, Congress appears to have made a conscious choice not to preclude such

actions. Defendants assertion that Congress intended, without so saying, to limit states longstanding ability to allow private remedies for violations of their own laws has no support in either statutory language, legislative history, or case law – and therefore defendants have not overcome the strong presumption against preemption applicable here, as is their burden (*Medtronic, supra,* 518 U.S at p. 485, 116 S.Ct. 2240; *Viva! International, supra,* 41 Cal.4th at p. 936, 63 Cal.Rptr.3d 50, 162 P.3d 569). We accordingly hold that section 337 does not impliedly preempt private actions based on violations of state laws explicitly authorized by section 343-1.

III. DISPOSITION

The judgment of the Court of Appeal is reversed and the matter is remanded to that court for further proceedings consistent with this opinion.

WE CONCUR: KENNARD, Acting C.J., BAXTER, WERDEGAR, CHIN, CORRIGAN and MIHARA, JJ.*

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* Associate Justice, Court of Appeal, Sixth Appellate District, assigned by the Acting Chief Justice pursuant to *article VI, section 6 of the California Constitution.*

142 Cal.App.4th 805

Court of Appeal, Second District,
Division 3, California.

FARM RAISED SALMON CASES.

No. B182901.

Aug. 31, 2006.
Review Granted Dec. 13, 2006.

Hagens Berman Sobol Shapiro, Los Angeles, Craig R. Spiegel, Lee M. Gordon, Elaine T. Byszewski, Los [sic] and Steve W. Berman, for Plaintiffs and Appellants.

Bill Lockyer, Attorney General, Albert Norman Shelden, Assistant Attorney General, and Ronald A. Reiter, Deputy Attorney General as Amicus Curiae on behalf of Plaintiffs and Appellants.

Akin Gump Strauss Hauer & Feld, Rex S. Heinke, David C. Allen, Johanna R. Shargel, Los Angeles; Streeter & Nangano, Thomas Barclay, Michael Nangano, Michael L. Coates, Los Angeles; Greenberg, Glusker, Fields, Claman, Machtinger & Kinsella, Norman Howard Levine, Los Angeles; Ervin, Cohen & Jessup, Allan B. Cooper, Beverly Hills, Tamara L. Dewar, Encino; O'Melveny & Myers, Carla J. Christofferson, Los Angeles; Seyfarth Shaw, Jay W. Connolly, San Francisco, and Geoff S. Long, for Defendants and Respondents.

CROSKEY, J.

Several individuals commenced separate actions against owners and operators of grocery stores alleging that the defendants sold artificially colored farmed salmon without disclosing to consumers the artificial coloring. The actions were coordinated in Farm Raised Salmon Cases, Judicial Council Coordination Proceeding No. 4329. The plaintiffs filed a coordinated complaint alleging as a class and representative action counts for unfair competition, violation of the Consumers Legal Remedies Act (CLRA) (Civ.Code, § 1750 et seq.), false advertising, and negligent misrepresentation. The superior court sustained a demurrer to the complaint on the grounds that the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 301 et seq.) preempted each cause of action, that the dispute should be referred to the United States Food and Drug Administration (FDA) or the California Department of Health Services (DHS) under the primary jurisdiction doctrine, and that the plaintiffs failed to state a cause of action for violation of the CLRA. In finding preemption the court relied primarily on section 337(a) of title 21 United States Code (section 337(a)), which states that an action to enforce the FDCA must be by and in the name of the United States. The plaintiffs appeal the judgment.

We conclude that in section 337(a) Congress made clear its intention to preclude private enforcement of the FDCA, that a state law private right of action based on an FDCA violation would frustrate the purposes of exclusive federal and state governmental

prosecution of the act, and that section 337(a) impliedly preempts all of the plaintiffs' causes of action. We therefore affirm the judgment without reaching or discussing the other grounds asserted by the defendants in support of their demurrer.

FACTUAL AND PROCEDURAL BACKGROUND

The plaintiffs in their consolidated and amended complaint filed in March 2004 allege that fish farmers feed farmed salmon the chemicals canthaxanthin and astaxanthin to obtain a color of flesh resembling that of wild salmon. They allege that the flesh of farmed salmon would appear grayish without the chemical additives and that consumers believe that the color of salmon is an indication of its origin, quality, freshness, flavor, and other characteristics. They allege that concerns have been raised about the potential health risks of consuming the artificial coloring agents in particular and farm-raised salmon in general. The plaintiffs allege that the FDCA and parallel state laws require food labeling to state that farmed salmon is artificially colored and that the defendants have failed to comply with those requirements. They allege that the failure to disclose the artificial color has caused consumers to believe that farmed salmon is wild salmon.

The complaint alleges counts for (1) unfair and unlawful business acts and practices in violation of the unfair competition law (Bus. & Prof.Code, § 17200 et seq.); (2) unfair or deceptive trade practices under

the CLRA; (3) false and misleading advertising in violation of the false advertising law (Bus. & Prof.Code, § 17500 et seq.); and (4) negligent misrepresentation. The laws alleged to be violated as a predicate for the unfair competition law count include provisions of the FDCA and California's Sherman Food, Drug, and Cosmetic Law (Sherman Law) (Health & Saf.Code, § 109875 et seq.), a provision of the CLRA, and Penal Code section 383. The complaint alleges a representative and class action on behalf of the plaintiffs and others similarly situated.

The defendants jointly demurred to the complaint on several grounds, including that (1) section 337(a) expressly precludes a private right of action to enforce the FDCA and therefore impliedly preempts an action under state law by a private party based on an FDCA violation, and each count of the plaintiffs' complaint is based on alleged violations of the FDCA, so section 337(a) preempts all of the counts alleged in the complaint;[1] (2) FURTHER CONSIDERATION of the plaintiffs' complaint by the court could conflict with regulation and enforcement by the FDA or DHS, which have special competence in the area of food

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[1] The defendants initially argued in support of their demurrer that section 337(a) expressly preempted each cause of action alleged in the complaint because it expressly precluded a private right of action, but later argued in reply that the express prohibition of a private right of action in section 337(a) "creates a conflict with the FDCA." That is, defendants now rely on "conflict" rather than "express" preemption. (See discussion, *post.*)

labeling, so the action should be dismissed under the primary jurisdiction doctrine; and (3) the plaintiffs failed to allege an affirmative representation as required in order to state a cause of action under Civil Code section 1770, subdivision (a)(5), (14) or (17). The defendants also moved to strike portions of the complaint.

The trial court sustained the demurrer to each count, with leave to amend, in an order filed on January 13, 2005. The court stated in its order that an alleged violation of the FDCA cannot provide the basis for a claim under the unfair competition law because section 337(a) "*explicitly bars a private right of action,*" quoting from our opinion in *Stevens v. Superior Court* (1999) 75 Cal.App.4th 594, 606, 89 Cal.Rptr.2d 370. The order further stated that section 337(a) precludes private enforcement of the FDCA, that alleged violations of the FDCA are the sole basis for each count alleged in the complaint, and that section 337(a) therefore preempts each count. The court rejected the plaintiffs' arguments that the primary jurisdiction doctrine does not apply and concluded that the doctrine applies. The court also concluded that a claim under the CLRA must be based on an affirmative statement of fact rather than an omission, and that the plaintiffs failed to allege an affirmative statement of fact.

The plaintiffs elected not to amend their complaint, but to challenge the sustaining of the demurrer on appeal from the judgment. The court entered a judgment of dismissal with prejudice on March 4,

2005. The plaintiffs have appealed from that judgment.

CONTENTIONS

The plaintiffs contend (1) section 337(a) neither expressly nor impliedly preempts their state law causes of action; (2) the primary jurisdiction doctrine does not apply, and even if it did apply it would support only a stay rather than dismissal; (3) the complaint alleges facts sufficient to state a cause of action under the unfair competition law based on unfair, fraudulent, and unlawful business acts or practices; and (4) the undisclosed artificial coloring of farmed salmon is itself a false representation concerning its origin within the meaning of the CLRA. The defendants dispute each of these contentions and assert the arguments that they raised in the trial court.

DISCUSSION

1. *Standard of Review*

We independently review the ruling on a demurrer and determine de novo whether the pleading alleges facts sufficient to state a cause of action. (*McCall v. PacifiCare of Cal., Inc.* (2001) 25 Cal.4th 412, 415, 106 Cal.Rptr.2d 271, 21 P.3d 1189.) We assume the truth of the properly pleaded factual allegations, facts that reasonably can be inferred from those expressly pleaded, and facts of which judicial notice can be taken. (*Schifando v. City of Los*

Angeles (2003) 31 Cal.4th 1074, 1081, 6 Cal.Rptr.3d 457, 79 P.3d 569.) We construe the pleading in a reasonable manner and read the allegations in context. (*Ibid.*)

The sustaining of the demurrer also encompassed a ruling on preemption. Preemption presents a question of law concerning statutory construction and legislative intent, which we review de novo. (*Spielholz v. Superior Court* (2001) 86 Cal.App.4th 1366, 1371, 104 Cal.Rptr.2d 197.)

2. *Preemption Principles*

The supremacy clause of the United States Constitution (art. VI, cl. 2) grants Congress the power to preempt state law. (*Crosby v. National Foreign Trade Council* (2000) 530 U.S. 363, 372, 120 S.Ct. 2288, 147 L.Ed.2d 352.) Federal preemption is a question of congressional intent. (*Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700; *English v. General Electric Co.* (1990) 496 U.S. 72, 78-79, 110 S.Ct. 2270, 110 L.Ed.2d 65.) Particularly in a field traditionally occupied by the states such as the exercise of a state's police powers, Congress's intent to preempt state law must be "clear and manifest." (*Medtronic, supra,* at p. 485, 116 S.Ct. 2240.) Consumer protection laws such as the unfair competition law, false advertising law, and CLRA, are within the states' historic police powers and therefore are subject to the presumption against preemption. (*Washington Mutual Bank v. Superior Court* (2002) 95

Cal.App.4th 606, 613, 115 Cal.Rptr.2d 765; *Black v. Financial Freedom Senior Funding Corp.* (2001) 92 Cal.App.4th 917, 926, 112 Cal.Rptr.2d 445.) That presumption applies not only to the question of whether Congress intended to preempt state law, but also to the scope of preemption. (*Medtronic, supra,* 518 U.S. at p. 485, 116 S.Ct. 2240) The party asserting that a federal law preempts a state law bears the burden to demonstrate preemption. (*Bronco Wine Co. v. Jolly* (2004) 33 Cal.4th 943, 956, 17 Cal.Rptr.3d 180, 95 P.3d 422.)

Congress's intent to preempt state law may be stated expressly, or it may be implied if a federal law demonstrates an intent to "occupy the field" or a state law conflicts with a federal law. (*Crosby v. National Foreign Trade Council, supra,* 530 U.S. at p. 372, 120 S.Ct. 2288.) The existence of an express preemption clause implies that Congress did not intend to preempt other matters, but does not necessarily negate the possibility of field or conflict preemption. (*Sprietsma v. Mercury Marine* (2002) 537 U.S. 51, 64-65, 123 S.Ct. 518, 154 L.Ed.2d 466; *Freightliner Corp. v. Myrick* (1995) 514 U.S. 280, 288, 115 S.Ct. 1483, 131 L.Ed.2d 385.) Congressional intent to occupy the field "may be inferred from a 'scheme of federal regulation . . . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it,' or where an Act of Congress 'touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same

subject.' [Citation.]" (*English v. General Electric Co., supra,* 496 U.S. at p. 79, 110 S.Ct. 2270.) In a field "'traditionally occupied by the States,' congressional intent to supersede state laws [by occupying the field] must be '"clear and manifest."' [Citation.]" (*Ibid.*) Conflict preemption exists where state law conflicts with federal law so that compliance with both the state and federal laws is impossible, or where the state law "'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" (*Crosby, supra,* at p. 373, 120 S.Ct. 2288.) Again, the presumption against preemption applies in a field traditionally occupied by the states, so conflict preemption must be clear and manifest. (*Bronco Wine Co. v. Jolly, supra,* 33 Cal.4th at p. 958, fn. 12, 17 Cal.Rptr.3d 180, 95 P.3d 422.)

3. *Section 337(a) Preempts Each Count Alleged in the Complaint*

The FDCA prohibits, among other things, the misbranding of food in interstate commerce. (21 U.S.C. § 331(b).) A food is considered misbranded if "its labeling is false or misleading in any particular" (*id.*, § 343(a)) or "it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact, except that to the extent that compliance with this paragraph is impracticable" (*id.*, § 343(k)). A federal district court may enjoin a violation of section 331 and in some cases may impose criminal penalties, and the offending food article may be seized. (*Id.*, §§ 332, 333(a) &

(d), 334.) A proceeding to enforce the FDCA or to restrain a violation must be commenced by and in the name of the United States, except that a state may commence a proceeding for the civil enforcement of, or to restrain a violation of, certain provisions after giving notice to the federal government. (*Id.*,§ 337(a) & (b).)[2]

Section 337(a) does not *expressly* state that state laws are preempted, but states that an action to enforce the FDCA must be by and in the name of the United States. Section 337(a) thus precludes a private right of action to enforce the FDCA. (*Pacific Trading Co. v. Wilson & Co., Inc.* (7th Cir.1976) 547 F.2d 367, 370; *see Buckman Co. v. Plaintiffs' Legal Committee* (2001) 531 U.S. 341, 349, fn. 4, 352, 121 S.Ct. 1012, 148 L.Ed.2d 854.) As the United States Supreme Court stated in *Buckman,* section 337(a) is "clear evidence that Congress intended that the [FDCA] be enforced exclusively by the Federal Government." (*Buckman, supra,* at p. 352, 121 S.Ct. 1012.)

The Sherman Law also prohibits the misbranding of food (Health & Saf.Code, § 110765) in language

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[2] "Except as provided in subsection (b) of this section [describing the limited circumstances where a state government may prosecute an action to enforce or restrain violations of the FDCA and the conditions imposed thereon], all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. . . ." (21 U.S.C. § 337(a).)

that parallels that of the FDCA. A food is considered misbranded if "its labeling is false or misleading in any particular" (*id.*, § 110660) or "it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless its labeling states that fact" (*id.*, § 110740). The Sherman Law also states that "[a]ll food labeling regulations" adopted pursuant to the FDCA "shall be the food labeling regulations of this state" and that the DHS may adopt additional regulations. (Health & Saf.Code, § 110100, subds. (a) & (b).) The DHS may issue a complaint to impose a civil penalty against any person charged with a violation of the Sherman Law or its implementing regulations, that person is entitled to an administrative hearing conducted pursuant to the administrative adjudication provisions of the Administrative Procedures Act (Gov.Code, § 11400 et seq.), and the decision of the DHS is subject to judicial review. (Health & Saf.Code, §§ 111855, 100171.) The Sherman Law states that the DHS or any other person also may commence an action in the superior court for an injunction to restrain a violation of the Sherman Law. (*Id.*, §§ 111900, 111910.) If the action is brought by the Attorney General or a district attorney, the court may impose a civil penalty. (*Id.*, § 111915.)

In section 337(a), Congress clearly expressed its intention to preclude private enforcement of the FDCA. By providing that only the federal government and, in some limited circumstances and only after giving notice to the federal government, a state may commence an action to enforce the FDCA, Congress

reserved for the federal government and the states the discretion to enforce or not enforce the FDCA in any particular set of circumstances and afforded the federal government a degree of oversight of the enforcement of the act. To allow a private person to prosecute a state law private right of action *based on a violation of the FDCA* would interfere with that governmental prosecutorial discretion and federal government oversight and conflict with the clear congressional intent to provide for a comprehensive and exclusive governmental enforcement scheme. These circumstances seem to demonstrate that a state law private right of action based on a violation of the FDCA necessarily would conflict with section 337(a). (*See Summit Technology v. High-Line Medical Instruments* (C.D.Cal.1996) 922 F.Supp. 299, 306, 316 [claims under California's unfair competition law and false advertising law based on conduct that violated the FDCA were "an attempt to assert a private right of action where none exists"]; *Animal Legal Defense Fund v. Provimi Veal Corp.* (D.Mass.1986) 626 F.Supp. 278, 283 [state law claims based on violations of the FDCA and a parallel Massachusetts statute were preempted because the FDCA precludes a private right of action].)

We reject the Attorney General's argument that section 337(a) only restricts standing in an action to "*directly* enforce" the FDCA. In our view, by precluding a private right of action "for the enforcement, or to restrain violations, of this chapter," section 337(a) necessarily "conflicts" with any private state law

cause of action that is *based on a violation of the FDCA.*

The plaintiffs' count for violation of the unfair competition law is clearly predicated on alleged violations of the FDCA and the Sherman Law. The "unlawful" prong of the unfair competition law authorizes a cause of action based on a violation of another statute even if there is no private right of action under the other statute. (*Stop Youth Addiction, Inc. v. Lucky Stores, Inc.* (1998) 17 Cal.4th 553, 562, 71 Cal.Rptr.2d 731, 950 P.2d 1086.) "[I]t is in enacting the UCL itself, and not by virtue of particular predicate statutes, that the Legislature has conferred upon private plaintiffs 'specific power' [citation] to prosecute unfair competition claims." (*Ibid.*) The mere absence of a private right of action to enforce a statute therefore does not preclude a right of action under the unfair competition law based on a violation of the predicate statute.

Federal preemption, however, is another question. A private right of action under the unfair competition law based on an alleged violation of the FDCA or the parallel provisions of the Sherman Law would conflict with the clear congressional intent to preclude private enforcement of the federal act. In our view, if the alleged conduct would constitute a violation of the FDCA, a private right of action under the unfair competition law challenging the same conduct would interfere with the exclusive prosecutorial discretion of the federal and state governments with respect to FDCA violations, frustrate the federal

government's oversight of the act's enforcement, and conflict with the clear congressional intent to preclude a private right of action based on an FDCA violation.

The plaintiffs allege in their operative complaint that the defendants have failed to disclose that farmed salmon offered for sale was artificially colored by use of canthaxanthin and astaxanthin in the fish feed, in violation of the FDCA and the Sherman Law, and that the same conduct also constitutes unfair and unlawful business acts and practices under the unfair competition law, unfair or deceptive trade practices under the CLRA, false and misleading advertising in violation of the false advertising law, and negligent misrepresentation. Put somewhat differently, the plaintiffs rely upon, and in order to recover under any count in their complaint would necessarily have to prove, facts reflecting one or more violations of the FDCA. This is true even though, as the Attorney General emphasizes, the plaintiffs are actually seeking recovery under the provisions of state law. The Attorney General argues that such allegations constitute a permissible "indirect" enforcement of the federal act that is not subject to preemption. The critical issue, however, is not whether the plaintiffs' complaint is seeking "direct" or "indirect" enforcement of the federal act, but whether the defendants' conduct upon which the plaintiffs' claims rest involves violations of the FDCA that the plaintiffs will necessarily have to prove in order to recover under their state law claims. Thus, the proper standard to be

applied rests upon what facts the plaintiffs will be required to prove under the allegations of their complaint. If those facts demonstrate violations of the FDCA, then preemption will apply irrespective of the particular state law theories of recovery relied upon by the plaintiffs. To hold otherwise would sanction a patent evasion of section 337(a) and would permit the plaintiffs to do the very thing that adherence to federal law would preclude.

We therefore conclude that all of the plaintiffs' state law causes of action are preempted. The plaintiffs allege no factual basis for any of their causes of action apart from the alleged conduct of the defendants which, if true, would violate one or more provisions of the FDCA. As a result, those causes of action are all preempted.[3] Thus, the trial court's sustaining of the demurrer to each count was proper based on preemption. Accordingly, we need not reach or consider the other grounds relied upon [sic] the court.

DISPOSITION

The judgment is affirmed. The defendants are entitled to recover their costs on appeal.

KLEIN, P.J., and ALDRICH, J., concur.

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[3] The plaintiffs acknowledge that their state law claims "incorporate and/or parallel federal food labeling standards."

SUPERIOR COURT OF THE
STATE OF CALIFORNIA
FOR THE COUNTY OF LOS ANGELES

COORDINATED PROCEEDING SPECIAL TITLE (RULE 1550(B))	JCCP 4329
FARM RAISED SALMON CASES	**ORDER SUSTAINING JOINT DEMURRER WITH LEAVE TO AMEND**
JENNIFER KANTER, et al., Plaintiffs, vs. SAFEWAY INC., et al., Defendants.	(Filed Jan. 13, 2005)

The Defendants' Joint Demurrer to the Consolidated Amended Complaint and the Joint Motion to Strike Portions of the Consolidated Amended Complaint came on regularly for hearing on November 29, 2004 at 2:00 PM in Department 309 of the above-entitled court, the Honorable Anthony J. Mohr, Judge Presiding. Jay W. Connolly of Seyfarth Shaw, LLP, Allan B. Cooper of Ervin, Cohen & Jessup, LLP, Michael L. Coates of Streeter & Nangano, Norman H. Levine of Greenberg, Glusker, Fields, et al., Paul W. Davies of O'Melveny and Meyers, LLP and David C. Allen of Akin Gump Strauss Hauer & Feld, LLP appeared on behalf of the Defendants. Kevin Roddy

and Elaine T. Byszewski of Hagens Berman appeared on behalf of Plaintiffs.

BACKGROUND

In these coordinated actions, Plaintiffs claim Defendants sell farm-raised salmon without disclosing that the feed on which the salmon were raised contained the color additives canthaxanthin and/or astaxanthin. The Complaint alleges four causes of action: (1) unfair competition in violation of Business and Professions Code ("B & P") §17200; (2) violation of the Consumer Legal Remedies Act ("CLRA"), Civil Code § 1770(a); (3) violation of B & P §17500; and (4) negligent misrepresentation.

Each of Plaintiffs' claims seeks relief based on Defendants' alleged violations of the federal Food, Drug and Cosmetic Act ("FDCA"), the United States Food and Drug Administration's (FDA) color additive regulations promulgated thereunder, and Defendants' alleged violations of California's Sherman Food, Drug, and Cosmetic Laws ("The Sherman Laws").[1] The California Sherman Laws adopt the FDA's color

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[1] The Sherman Laws incorporate by reference all color additive regulations promulgated by the FDA pursuant to the FDCA. *See* Health and Safety Code § 110090 ("All color additive regulations and any amendments to the regulations adopted pursuant to the federal act in effect on November 23, 1970, or adopted on or after that date, are the color additive regulations of this state.").

additive regulations *in toto* without any amendments at all.

Defendants allegedly failed to comply with the FDA regulations by not labeling farm-raised salmon sold in their stores with the phrase "color added," or some similar wording. Plaintiffs further aver that had Defendants complied with the FDA's labeling requirements, Plaintiffs and the putative class members would not have purchased the farm-raised fish.

DISCUSSION

The California Laws on which Plaintiffs Rely are Preempted

In *Stop Youth Addiction, Inc. v. Lucky Stores, Inc.*, 17 Cal. 4th 553 (1998), the California Supreme Court held that our Unfair Competition Law "cannot be used to state a cause of action the gist of which is absolutely barred under some other principle of law." 17 Cal. 4th at 566. Based on *Stop Youth Addiction*, the Court of Appeal has observed that "the UC[L] allows ***nearly*** any law or regulation to serve as its basis ***unless the predicate statute explicitly bars a private right of action***, or the defendant is otherwise privileged or immune." *Stevens v. Superior Court*, 75 Cal. App. 4th 594, 603-04, 606 (1999). This suggests that if the FDCA prohibits private litigants from suing over noncompliance with the FDA's regulations, then Plaintiffs' UCL claim cannot borrow violations of the FDCA and its attendant regulations.

Section 337(a) of the FDCA states: "Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). The United States Supreme Court has stated that the FDCA "leaves no doubt that it is the Federal Government rather than private litigants" who are authorized to file suit for noncompliance with the FDA's regulations. *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4. (2001), *citing* 21 U.S.C. § 337(a). Thus, pursuant to 21 U.S.C. § 337(a) and *Buckman*, and following the principles set forth in *Lucky Stores* and *Stevens*, the UCL cannot borrow violations of the FDCA or the FDA's regulations on food labeling promulgated thereunder.

The only exception to exclusive federal prosecution of FDA regulations is found in subsection (b)(1) of section 337: "A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State." However, the State may commence such an action only after giving the Secretary of Health & Human Services 30 days notice, during which the federal government may decide to commence its own action. 21 U.S.C. § 337(b)(2). No provision of law allows a private citizen to commence such an action, with or without notice to the federal authorities.

Even the exception set forth in section 337(b)(1) does not apply here. Section 343(m) deals with color additives, the subject matter of Health & Safety Code Section 110090, and it is not one of the exceptions to the federal enforcement exclusivity provision in Section 337(b)(1). Plaintiffs do not allege any independent common law or statutory duty to label farm-raised salmon as containing color additives other than what the FDA regulations contain. Resolution of each of Plaintiffs' causes of action will therefore turn on the FDA's regulations. In light of the prohibition against private suits to enforce the FDA's regulations, Plaintiffs' suit is barred.

Plaintiffs rely principally on *People v. McKale*, 25 Cal. 3d 626 (1979) and *Samura v. Kaiser Foundation Health Plan, Inc.*, 17 Cal. App. 4th 1284 (1993) to argue that "it is entirely permissible for a UCL claim to be based upon violations of an underlying state or federal statute (such as the FDCA) that does not permit private claims." The Court agrees with this proposition as a general statement of the law. However, cases like McKale support the *Stop Youth Addiction/Stevens* exception: that any law may serve as the predicate for a UCL claim "*unless the predicate statute explicitly bars a private right of action.*" *Stevens*, 75 Cal. App. 4th at 606. Any private action under the UCL that seeks to borrow FDCA standards is barred by § 337(a) of the FDCA. Accordingly, Plaintiffs cannot rely on cases that permit a UCL action merely because the tethered statute or regulation is silent absent a private right of action.

McKale and *Samura* are distinguishable on two other grounds. First, *McKale* held that the "lack of express authorization for a district attorney to prosecute violations of the Mobilehome Parks Act does not preclude prosecution of an action pursuant to applicable Business and Professions Code sections for unfair competition." 25 Cal. 3d at 633. *McKale* did not address the standing provision at issue in this case: the language of UCL section 17204 that empowers *private citizens* (as opposed to law enforcement officials) to seek injunctive relief for acts of unfair competition. That a district attorney may use the UCL to enforce a law he does not have the express authority to enforce (i.e., where the statute is silent regarding enforcement authority) does not mean that private plaintiffs have the same power under § 17204.

Second, the *Samura* court cautioned that "the courts cannot assume general regulatory powers over [defendants] through the guise of enforcing Business and Professions Code section 17200." *Samura*, 17 Cal. App. 4th at 1301-1302. The FDA and the DHS have specialized knowledge in the area of food labeling that is far beyond the expertise of the general public and (at least with respect to this judge) the bench.

Plaintiffs also rely on *Medtronic v. Lohr*, 518 U.S. 470 (1996), and two California cases that interpreted *Medtronic* to circumvent Congress' express prohibition of private attempts to enforce the FDCA and its implementing regulations. *Consumer Justice Center v. Olympian Labs Inc.*, 99 Cal. App. 4th 1056 (2002) and *Washington Mutual Bank v. Superior Court*, 75

Cal. App. 4th 773 (1999). Plaintiffs' argument fails to distinguish express preemption, which was the subject of *Medtronic*, from implied preemption.

The Supreme Court clarified its *Medtronic* decision in *Buckman*, *supra*, 531 U.S. 341. There, patients claiming to have suffered injuries from orthopedic bone screws in their spines brought suit alleging that a consultant to the bone screw manufacturer made fraudulent representations to the FDA in the course of obtaining approval to market the screws. Plaintiffs alleged that the misrepresentations played a substantial role in the events causing their injuries. The trial court held that the claims were an attempt to privately enforce the FDCA and conflicted with the prohibition against private enforcement actions in § 337(a).

The Third Circuit reversed and held that plaintiffs' state law claims were neither expressly nor impliedly preempted. The Supreme Court reversed, finding that the patients' state law claims were impliedly preempted by § 337(a) of the FDCA. In so holding, the Supreme Court distinguished *Medtronic* and reasoned that a difference exists between state laws that parallel federal FDA safety requirements and those seeking to enforce the FDA's disclosure requirements. The Court stated:

> It is clear that the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, **not solely from the violation of FDCA requirements.** *See* **518 U.S., at 481,**

> **116 S.Ct. 2240. In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements.** Thus, although Medtronic can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.
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> In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case. For the reasons stated above, we think this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme.
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> *Buckman*, 531 U.S. at 352-353.

As in *Buckman*, because Plaintiffs' claims are based solely on the presence of, and the Defendants' alleged failure to comply with, the FDA's labeling regulations promulgated under the FDCA, Plaintiffs' state law claims are preempted. Plaintiffs' UCL claims exist mainly by virtue of the FDCA labeling disclosure requirements, which were imported wholesale into the Health and Safety Code. Resolving Plaintiffs' claims will have to turn on Defendants' compliance with the FDA's regulations.

Medtronic was a product liability case in which plaintiff suffered injuries when the Medtronic pacemaker implanted in her heart failed. The trial court granted summary judgment to Medtronic based on §360k(a) of the MDA, which Congress expressed its intent to preempt certain state laws. *See* FDCA, 21 U.S.C. § 360k(a). The case at bar does not involve § 360k, which does not apply to food. The FDA's regulations occupy the field with regard to food labeling, including farm-raised salmon. In the area of medical devices, Congress left it to the FDA to define the scope of the preemptive effect of the MDA. This is not true for food regulation or § 337(a) of the FDCA. The FDA has not been granted the authority to define the preemptive effect of § 337(a). As such, the Supreme Court's analysis of § 360k(a) and (b) in *Medtronic* is inapplicable to the preemption issues presented by this demurrer.

Plaintiffs Fail to Allege a Private Right of Action Under The Sherman Laws

Health and Safety Code § 110090 adopts all of the FDA's color additive regulations that were promulgated pursuant to the FDCA, including those dealing with canthaxanthin and astaxanthin farm-raised salmon.[2] California incorporated the FDA's

[2] Pursuant to Health and Safety Code §110090, all color additive regulations adopted by FDA pursuant to the "federal act" are regulations of the State of California. The "federal act" is the FDCA. *See* Health and Safety Code § 109930.

regulations by reference *in toto*, without modification or amendment.

Plaintiffs fail to allege a private right of action under the Sherman Laws. First, just as the federal statute allows actions to be filed only by the federal government, 21 U.S.C. § 337(a), the state legislation left enforcement solely to the Attorney General, district attorneys and city attorneys. Health & Safety Code § 111840. Second, since the federal law precludes private enforcement, the enactment of an analogous state provision without specific reference to a private right of action reflects a legislative intention to follow federal law. "We must presume that when the Legislature enacted the ALRA, it was aware that the courts, not the National Labor Relations Board, adjudicated alleged violations of section 186." *United Farm Workers of America, AFL-CIO v. Dutra Farms*, 83 Cal.App.4th 1146, (2000). "When a state statute is modeled on a federal statute we presume the Legislature intended to adopt the construction employed by the federal courts." *In re M.S.*, 10 Cal.4th 698 (1995) *citing People v. Simon*, 9 Cal.4th 493, 511 (1995) and *Los Angeles Met. Transit Authority v. Brotherhood of Railroad Trainmen*, 54 Cal.2d 684, 688-689 (1960).

This court cannot find a case permitting private enforcement of Section 110090 or any of the similar Health & Safety Code provisions that incorporate federal regulations. The only case to address the issue, *Summit Technology v. High-Line Medical Instruments Co., Inc.*, 922 F. Supp. 299 (C.D. Cal.

1996) ("*Summit I*"), held that no private right of action is available under the Health & Safety Code.

Plaintiffs Fail to Allege an Action under Penal Code § 383

Plaintiffs also attempt to tether a section 17200 violation to what appears to be a sleeping statute, Penal Code § 383. To the extent that the language of Penal Code § 383 makes the use of FDA-approved color additives unlawful, it similarly is preempted by federal law. Adopted in 1872, this section makes it a crime to sell any adulterated food. Adulterated food is defined to include any food that is colored to enhance its appearance or value. The statute makes no exceptions for foods colored with color additives approved by the FDA for use in food. A violation occurs whether or not the presence of the color additive is disclosed. The scope of Penal Code § 383 arguably criminalizes the use of an FDA-approved color additive.

This conflict resembles that addressed in *Kanter v. Warner-Lambert Co.*, 99 Cal.App.4th 780, 796 (2002). Plaintiffs brought state law claims against a manufacturer of an over-the-counter treatment for head lice for allegedly false and misleading statements on the manufacturer's label. The FDA had approved the use of the label in question. *Id.* at 787. The Court held that to the extent the theories of liability under California state law outlawed or banned what the FDA allowed, the state law claims were preempted. Specifically, the Court held:

> While the legal theories underlying these causes of action may differ, each is bottomed on the assertion that this approved label is no longer accurate or adequate and that the label should be changed or the product banned. Each cause of action would result in the establishment of a state requirement regarding labeling that would be "different from" and "otherwise not identical with" the federally required label (Sec. 379r(a)), and each is therefore preempted. *Id.*

While *Kanter* dealt with a different section of the FDCA, it stands for the proposition that state law cannot create civil liability for use of products the FDA permits. Here Penal Code § 383 is preempted to the extent that it conflicts with the FDA regulations allowing the color enhancement of food.

The Primary Jurisdiction Doctrine

Plaintiffs oppose the primary jurisdiction of the FDA and the DHS by arguing that the primary jurisdiction doctrine does not apply because there are no "pending or anticipated administrative procedures concerning required disclosure standards for farm-raised salmon." *AICCO, Inc. v. Ins. Co. of North America*, 90 Cal. App. 4th 579, 594 (2001) did not decline to apply the primary jurisdiction doctrine because no pending or anticipated administrative procedure existed. Rather, the court declined to apply the doctrine because "the administrative bodies have already rendered whatever decision might be relevant

to the present suit [accordingly], there was no need to stay the action for further action by some administrative body." *AICCO*, 90 Cal. App. 4th at 594-595. The court declined because *there was no need for further recourse to those agencies*. Here, the FDA has already regulated labeling for the color additives at issue and has stated its intention with respect to mislabeling of color additives. *See* 21 C.F.R. §71.22

Plaintiffs Have Not Pleaded a Violation of the Consumer Legal Remedies Act

To violate the CLRA provisions on which Plaintiffs rely, one needs an affirmative statement of fact about a product or service, not mere omissions. Plaintiffs have failed to sufficiently plead that the Defendants made affirmative false statements.

Relying on *Saunders v. Superior Court*, 27 Cal. App. 4th 832 (1994) and *Motors, Inc., v. Times-Mirror Co.*, 102 Cal. App. 3d 735 (1980), plaintiffs argue that whether a defendant's actions amount to affirmative conduct is "a question of fact not properly resolved by demurrer." Neither *Saunders* nor *Motors, Inc.* includes any analysis of whether the alleged wrongdoing in those cases constituted an affirmative representation or merely an omission.

Plaintiffs cite *Outboard Marine Corp. v. Superior Court*, 52 Cal. App. 3d 30 (1975), for the proposition that the CLRA draws no distinction between affirmative representations and mere omissions. *Outboard Marine* cannot be read to support Plaintiffs' argument.

The seller of an all-terrain vehicle affirmatively represented certain performance specifications that the vehicle would achieve when driven in off-road areas. The purchaser brought an action because the vehicle failed to meet the affirmative representations. The purchaser pled two causes of action. One alleged that the seller's affirmative statements were false. The second alleged that the seller concealed the fact that the vehicle did not have the characteristics described in the seller's affirmative statements. The "concealment" cause of action was in essence the flip side of the affirmative misrepresentation cause of action. 52 Cal. App. 3d at 36-37. Based on the proposition that "[i]t is fundamental that every affirmative misrepresentation of fact works a concealment of the true fact," the *Outboard Marine* Court explained that the two causes of action allege, in different language, identical conduct. *Id.* By contrast, Plaintiffs' allegations of non-disclosure constitute the gravamen of the Complaint at bar.

CONCLUSION AND ORDER

The Joint Demurrer is SUSTAINED. The court doubts that the plaintiffs will be able to amend to state a cause of action. However, this not a situation in which the plaintiffs have already filed a number of amended complaints. In an abundance of caution, the

court will give plaintiffs 30 days leave to amend. The motion to strike is moot and taken off calendar.

Dated JAN 13 2005

ANTHONY J. MOHR
Anthony J. Mohr
Judge of the Superior Court

H.R. 3562, 101st Cong., 2d Sess. (1990)

UNITED STATES [SEAL] OF AMERICA

Congressional Record

PROCEEDINGS AND DEBATES OF THE *101st* CONGRESS
SECOND SESSION

VOLUME 136 – PART 14

JULY 26, 1990 TO JULY 31, 1990

(PAGES 19491 TO 20963)

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The SPEAKER, pro tempore. The gentleman from California [Mr. WAXMAN] will be recognized for 20 minutes, and the gentleman from Illinois [Mr. MADIGAN] will be recognized for 20 minutes.

The Chair recognizes the gentleman from California [Mr. WAXMAN].

GENERAL LEAVE

Mr. WAXMAN, Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks on H.R. 3562, the bill now under consideration.

The SPEAKER, pro tempore. Is there objection to the request of the gentleman from California?

There was no objection.

Mr. WAXMAN, Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, the purpose of this legislation is to make sense of the confusing array of nutrition labels that confront all consumers every time they enter the supermarket.

H.R. 3562 would require that food products disclose their nutritional content. Every food that is covered would have a uniform nutrition label that would disclose the amount of calories, fat, salt, and other nutrients. Where full labeling would be impractical, the bill provides for an exemption or requires that the information be provided in a modified form. Under this principle, restaurants are exempt from the nutrition labeling requirements. The information pertinent to fish, fruits, and vegetables would be conveyed by a sign or brochure made available at the supermarket, rather than by labeling on the food.

The bill also addresses the issue of nutrition claims on foods. First, content claims would have to be consistent with terms defined by the Secretary of the Department of Health and Human Services, who would presumably delegate this authority to the Commissioner of the Food and Drug Administration. Today, companies use terms such as "low" and "light" differently and inconsistently. On some products, "light" means low in fat; on others, such as some brands of olive oil, it refers to the color of the product. The bill would correct this deceptive and misleading state of affairs by requiring that terms such as "light" have a single meaning.

The second issue concerns disease claims. Today, a variety of disease claims are made on foods. An example would be the claim that bran prevents cancer. Under this bill, before such a claim could be made, the FDA would review the scientific evidence and decide whether the claim is valid. Once the FDA decides that a specific claim is valid, then any company could make a claim that was consistent with the FDA's findings.

Mr. Speaker, the bill before us has been substantially changed since it was reported by the Committee on Energy and Commerce. Those changes reflect negotiations between the committee and interested parties in the private sector. The legislative intent of those negotiations is reflected in a separate statement of intent of the changes that have been made to H.R. 3562 since the bill was reported by the Energy and Commerce Committee. That statement has been reviewed by both me and by Mr. MADIGAN, and it reflects our understanding of the changes that have been made.

I would like to say a word about the changes that have been made with respect to preemption of State laws because I believe that the compromise that we have negotiated reflects principles that we should adhere to in the future when addressing similar issues.

The first principle is that State laws should not be preempted unless the nature of the laws at issue makes it difficult and even impossible for companies

to operate in interstate commerce. In the case of food labeling laws at issue with regard to H.R. 3562, the food industry made a strong argument that this was the case. A national food processor understandably finds it difficult to comply with numerous conflicting and inconsistent State and local laws. This argument, which has particular appeal with respect to food labels, would have far less appeal where other types of preemption are at issue.

Second, the States should never be preempted unless a strong Federal regulatory system is in place. Under this principle, provisions for preempting the States on nutrition labeling and health claims were included in H.R. 3562 at the time it was reported out by the Subcommittee on Energy and Commerce.

However, the bill before the Members today contains provisions that would preempt other aspects of the food label, such as provisions regarding misleading containers and the prominence of labeling. Because we were unable to determine whether the Federal standard is strong in these areas, the bill provides for a study of Federal and State standards to determine whether additional Federal regulation is needed. If additional Federal regulation is deemed necessary, then the States will not be preempted until those regulations are in place.

Third, any preemption provision must recognize the important contribution that the State can make in regulation, and it must leave a role for the states.

H.R. 3562 recognizes the importance of the State role: by allowing States to adopt standards that are identical to the Federal standard, which may be enforced in State court; by allowing the States to enforce the Federal standard in Federal court; and by allowing the States to petition for permission to enforce a separate State law where the State demonstrates a particular need and where such a law would not unduly burden interstate commerce.

Fourth, and most importantly, the most compelling argument for State regulation is where the States have adopted laws to protect the safety of their citizens. Therefore, the preemption provisions in H.R. 3562 explicitly permit the States to adopt requirements for warning about the ingredients or components of food.

As a result of these negotiations, H.R. 3652 has strong support from both the public health organizations that have been active on nutrition issues and from the trade associations of food companies that will be affected by the bill. I have received letters of support from the American Bakers Association, the Food Marketing Institute, Grocery Manufacturers of America Inc., International Ice Cream Association, Milk Industry Foundation, the National American Wholesale Grocers Association, the National Food Processors Association, the National Grocers Association as well as the American Dietetic Association, American Heart Association, American Cancer Society, American Association of Retired Persons, and the Society for Nutrition Education.

I would like to say a final word about the work behind this bill. As is true of any important piece of legislation, H.R. 3562 is the result of hard work by many Members, some of whom have had their own legislative proposals in this area, specifically Mr. COOPER, Mr. SLATTERY, Mr. SMITH, and Mr. GLICKMAN.

There are two Members whose contribution I would particularly like to single out for special mention. The first is the gentleman from Massachusetts. Mr. MOAKLEY, who has championed the cause of nutrition information for many years and who introduced legislation which served as the progenitor of H.R. 3562 before our subcommittee even considered it.

The second Member I would like to thank is my friend, the gentleman from Illinois [Mr. MADIGAN], the principal cosponsor of this bill. From the time the bill was introduced, the gentleman from Illinois has worked tirelessly to ensure that the bill remains strong and that we do all we can to enact it into law. He has insisted that the bill be as effective as possible so that all Americans can be fully and fairly informed about the nutritional characteristics of the food that they eat.

Then last, I want to mention the contribution of the staff, particularly the minority staff, Mary McGrane, and our subcommittee counsel Bill Schultz.

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H.R. Rep. 101-538, 101st Cong., 2d Sess. (1990)

NUTRITION LABELING AND EDUCATION ACT OF 1990

JUNE 13, 1990. –Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. DINGELL, from the Committee on Energy and Commerce, submitted the following

REPORT

[To accompany H.R. 3562]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3562) to amend the Federal Food, Drug, and Cosmetic Act to prescribe nutrition labeling for foods, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

* * *

PURPOSE AND SUMMARY

The purpose of this legislation is to clarify and to strengthen the Food and Drug Administration's legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods. The bill covers only nutrients or substances in food that "nourish,"

and it does not in any way regulate carcinogens or other, non-nutritive substances in foods.

The bill would require that food products disclose the amount of specified nutrients in foods. Every covered food would have a uniform nutrition label disclosing the amount of calories, fat, salt and other nutrients. In order to make this information meaningful, the bill requires the FDA to issue standards providing that uniform serving size information and information concerning the number of servings be furnished on the food label.

Where full labeling is impractical, the bill provides for an exemption or requires that the information be provided in a modified form. Under this approach, restaurants are exempt from the nutrition labeling requirements. The information pertinent to raw fish, fruits and vegetables would be conveyed by a sign or brochure made available at the site of sale, rather than by a label on the food.

The bill also addresses the issue of claims that may be made about nutrients in foods. First, content claims (such as "low salt" or "light") would have to be consistent with terms defined by the Secretary of Health and Human Services ("HHS").

Second, the bill provides a process for the orderly regulation of disease claims (such as "fiber prevents cancer"). Under the bill, the Food and Drug Administration ("FDA") would review the scientific evidence and decide if the claim is valid. A disease claim may not be made unless it is consistent with a final regulation

issued by the FDA. Once the FDA decides that a specific claim is valid, any company can make a claim that is consistent with the FDA's findings.

The bill also contains a provision that would prevent State and local governments from adopting inconsistent requirements with respect to the labeling of nutrients or with respect to the claims that may be made about the nutrients in foods. However, these governmental entities are explicitly permitted to enforce Federal requirements with respect to nutrition labeling.

Finally, the bill requires the FDA to issue final regulations for implementation of the nutrition labeling and claims requirements within 18 months of enactment. Individuals and companies subject to the bill's provisions would be given six additional months to comply with the requirements.

The new nutrition labeling requirements would be administered by the Secretary of Health and Human Services through the FDA. The legislation would not alter existing law with regard to the division of jurisdiction between FDA and the U.S. Department of Agriculture.

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SECTION-BY-SECTION ANALYSIS AND DISCUSSION

Section 1 provides that the short title of the bill is the "Nutrition Labeling and Education Act of 1990."

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SECTION 4: STATE ENFORCEMENT

States are authorized to bring actions to enforce sections 2 and 3 (which add sections 403(q) and (r) to the FFDC Act) in the name of the State if the State notifies the Secretary at least 30 days before the proceeding is brought. The proceedings would be brought in Federal court and would supplement the FDA's enforcement capabilities.

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